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The contributory factors in drug errors and their reporting

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CHAPTER 1: INTRODUCTION TO THE THESIS

1.1 Aim of the study and research questions

The aim of this thesis is to examine the contributory factors in drug errors and their reporting so as to design an enhanced reporting scheme to improve the quality of reporting in an acute hospital trust. The related research questions are:

1. What are the contributory factors in drug errors?
2. How effective is the reporting of drug errors?
3. Can an enhanced reporting scheme, predicated on the analysis of local documentary and interview data, identify the contributory factors in drug errors and improve the quality of their reporting in an acute hospital trust?

The study aim and research questions reflect a growing consensus, articulated by Boaden and Walshe (2006), that patient safety research should focus on understanding the causes of adverse events and developing interventions to improve safety. Although there are concerns about the value of incident reporting (Wald & Shojania 2003, Armitage & Chapman 2007), it would appear that error reporting systems remain a high priority in advancing patient safety (Kohn et al 2000, Department of Health 2000a, National Patient Safety Agency 2004, WHO & World Alliance for Patient Safety 2004), and consequently it is the area chosen for intervention in this study. Enhancement of the existing scheme is based on a greater understanding of drug errors, their causation, and their reporting.

1.2 Research design

It is proposed that by establishing a knowledge of the contributory factors in drug errors that a reporting process can be improved; conversely, improving a reporting process can improve the identification of contributory factors. The ultimate goal of this study is to produce an enhanced drug error reporting scheme.

The research design is in three stages:

1. Retrieval and analysis of a random sample of 50% of all incident reports submitted to a risk management department over a five year period (1999-2003)
2. Interviews with a purposive sample of 40 health professionals, who had all experienced drug errors and were involved in either the prescribing, dispensing, or administering of drugs to patients or the management of these activities
3. Design and piloting of an enhanced drug error reporting scheme

This study is sequential. The documentary analysis (stage one) examines the type and nature of reported drug errors and their reporting, this is explored further with practitioners through in-depth interviews (stage two) using an interview schedule that was derived from the report data. The data from stages one and two jointly inform the design of the enhanced reporting scheme piloted in stage three. The study draws on a range of methods and by doing so acknowledges that a single method is generally insufficient to tackle the multi-faceted and complex nature of patient safety (Grol et al 2004).

Patient safety research also requires a multi-disciplinary approach (Boaden & Walshe 2006). The approach taken in this thesis supports that position. Although it has not been carried out by a multi-disciplinary team, the primary supervision has combined both medical (Professor John Wright) and nursing (Professor Robert Newell) perspectives and continuous guidance has also been provided by a human factors psychologist (Dr Rebecca Lawton) and the Director of Pharmacy in the research setting. Moreover, the data has been collected from multi-disciplinary documents and a multi-disciplinary sample of health professionals both in the interviews, and the subsequent piloting of the enhanced reporting scheme.

1.3 Overview of the drug errors and their reporting

The NHS spends over £10 billion a year on prescription drugs, which translates into over 800 million prescriptions (Office for Fair Trading 2007). The plethora of drugs and drug regimes, increasingly delivered as part of a complex array of treatment – often unmediated by automated safeguards - can place both patients and professionals in a relatively vulnerable position. Although society and the healthcare professions may have difficulty accepting this notion (Naylor 2002), recourse to human error theory and the rapidly building patient safety research base suggests that although the situation can be much improved, there is no perfect solution.

Drug errors appear to be the single most common type of medical error, and many are life threatening (Leape et al, 1991, Naylor 2002). The growth of patient safety initiatives at both local and national level reflects the general concern. The reporting of errors is seen as one means of improving patient safety (Donaldson 2006).

Like many other error types however, they are under-reported (Vincent 2006). This situation is often conceptualised as the medication error iceberg (DoH 2004) where there is little knowledge of the incidence of drug errors but if noticed, many are deemed insignificant – especially those which do not impact on the patient. Essential in any analysis is a consideration of the contributory factors in such errors which should include the role of individuals, the clinical context, and the overarching organisational systems (Vincent et al 2000).

1.4 Structure of the thesis

The thesis consists of ten chapters. Owing to the sheer volume of information around the study topic and the diversity of literature in the field of human error and healthcare, the literature is reviewed in two chapters. Chapter 2 provides the

background to the topic and is written in the style of a narrative review. This chapter describes the development of human error theory and its application to health care. The definition of drug error and other closely related terms are discussed prior to an overview of the epidemiology of drug errors. The purpose, nature, and challenges of incident reporting in and outside of health care are also discussed which contextualises the specific research questions addressed. Finally, the key methodological issues in medical and drug error research are discussed before considering the epistemological and ethical considerations for this study. Chapter 3 is dedicated to two specific systematic reviews focussed on the contributory factors in drug errors; and drug error reporting.

As there were three separate but sequential stages to the study, there are three separate method chapters (Chapters 4, 6, and 8) each followed by a chapter on the respective findings (Chapters 5, 7, and 9). Chapter 10 presents a combined discussion of the findings from stages one and two to facilitate a more accessible and unified view of the implications. This is followed by a brief discussion on the process and outcome of the mini-pilot – its design based on the preceding empirical work and the reviewed literature. The study's strengths and limitations are then given. The final chapter also offers a brief conclusion to the study with some recommendations.

CHAPTER 2: BACKGROUND LITERATURE

2.1 Introduction

This chapter is written in the style of a narrative review. The purpose of this chapter, in common with such a review is to describe the development of a research topic, its context and theoretical underpinning (Cook et al 1997). This chapter also provides a foundation for the forthcoming systematic review (Chapter 3), by exploring a range of literature that is too diverse for a systematic review but is germane to the research questions identified in Chapter 1. There are four main sections:

- Human error theory: concept, assumptions and critical appraisal
- Drug errors and reporting systems
- Epidemiology of medical and drug errors
- Specific epistemological and ethical considerations

2.2 The concept of human error

The word 'error' is commonly associated with individual misgivings, for example, 'to see the error of one's ways' implies that a person has engaged in some wrongdoing. In the latter part of the 20th century however, the word may, to some extent, have been depersonalised. In computing and other more technical domains, it is used in relation to the failure of *systems*, yet elsewhere the word still stimulates pejorative connotations for any individuals involved. To more fully appreciate the concept of error, a historical grounding is necessary.

In 1620 Francis Bacon proposed that the human mind assumes far more order and regularity in the world than it should – which was perhaps the origin of subsequent theories which have strongly suggested that the memory is biased towards over-regularisation and overgeneralization (Norman, 1988). Of course this is not a

completely counterproductive state, as it would be impossible to store a library of completely individualised memory files specifically allocated to each and every experience. That said, it points towards some of the initial assumptions about accident causation, that there is a human component and that human memory and other thought processes would be predominant factors.

In the early part of the last century, Greenwood and Woods (1919) carried out the first statistical studies of accident proneness. They hypothesised that certain individuals experienced accidents because of a particular susceptibility, which was in turn, owing to their personalities. Lawton and Parker (1998) have since demonstrated that the context of their work had a clear bearing on their conclusions. Greenwood and Woods' report, submitted to the government of the day, was not based on studying men at their physical peak - many of whom had been drafted into the armed forces - but on very young or old men who were operating machinery with ever-increasing speeds in repressive high-risk conditions, and against the clock. The research findings conveniently supported a potent strategy for many factory managers: dismiss those workers who were thought to be inherently flawed whilst ignoring any responsibility for providing safe working conditions. Similar theorising continued in other statistical studies between the wars, when it was still held that accident prone individuals suffered accidents both in work and at home. However, the researchers discounted that their findings were based on self-reporting and thus did not include all those individuals who suffered accidents but did *not* report; furthermore the level of risk exposure in the so called accident prone groups was ignored (Lawton & Parker, 1998). Findings of this kind probably helped lay the foundations for focussing blame on those proximal to the error, or what is known as the 'sharp end' (Reason 1997b, p10, Reason 2000, p768). Reason (1974) refined these early theories by looking at what were subsequently termed 'accident repeaters' yet found little consistency of pattern; in short, those who might have a flurry of accidents may then become accident free or

vice-versa. A theory was emerging that accidents might depend on a combination of factors and circumstances. Moreover, there was no normal distribution of accident rates; they differed according to the experience of individuals, the nature of their work and numerous other environmental factors. This served to isolate the premise that situations rather than individuals are error-prone – more recently thought to be epitomised in the repeated cases of wrong route injections of vincristine in the UK (Reason, 2004).

Focussing on the cognitive processes that predispose to error, but in combination with an explicit acknowledgement of organisational, environmental or systems factors, there has been a shift from blaming individuals and towards an acceptance of the inevitability of error. Reason in particular has applied this theory to healthcare (Reason 2000, 2004) and strongly influenced the British Department of Health's policy perspective on medical error where a string of high profile incidents had demanded a fresh approach to the issues – learning from incidents and moving away from a disciplinary-centred policy (DoH, 2000a). Although sceptical health professionals might view the application of Reason's perspective to healthcare, where the terrain is unpredictable and comprised of many uncontrolled variables – including the patient (Vincent 2006) as ill fitting, there is common ground with other sectors where organisational structures and processes, as well as environmental pressures are often prominent in causation (West, 2000). Furthermore, error emanates from the very same cognitive processes and behaviours that do not lead to error (Vincent 2006), crystallising the premise that 'to err is human' (Pope, 1711). While there are clearly a number of considerations in conceptualising human error, error nevertheless demands a pragmatic definition which does not inappropriately personalise. It is argued here that Reason has achieved this in his seminal textbook on human error where he proposed that error is:

'the failure of a planned action to be completed as *intended* – without the intervention of some unforeseeable event; or the use of a wrong plan to achieve an

aim' (Reason 1990, p9).

The breadth of this definition has been described as helpful by Rubin et al (2003) who suggested it should lead to high error capture, yet this is seen by others as a potential weakness in a medical context (Kuzel et al 2003), which will be expanded upon in Section 2.4.

Reason's theoretical perspective shares and acknowledges common ground with previous work by Norman (1981, 1988) on errors in action, Perrow (1984) on normal accidents, Rasmussen (1974, 1990) on levels of human performance and reliability, and Weick (1987) on high reliability organisations. The combined work of Norman and Reason has given rise to the categorisation of what are invariably automatised cognitive phenomena which illuminate the individual but usually covert, *process* of error. Norman's position has been developed through specifically focussed empirical research using largely experimental methods (Norman 1981), whereas Reason has then synthesised the available knowledge of individual factors *with* system factors, examining their relationship so as to expose the way in which sometimes apparently robust defences are breached. This position underlines the complexity of error, and the difficulties in identifying causation which will be discussed further. This perspective is sometimes called 'human factors' (Vincent 2006, p25). Following Parker and Lawton (2003), it will be referred to here as human error theory.

2.2.1 Error and cognition

There are two prominent models of mental performance which facilitate the analysis of human error: the first splits performance into three levels, often depending on the performer's prior experience and the situation in which they find themselves. The second highlights the problems that can occur in planning or activating such a performance, [i.e. slips, lapses, and mistakes]. Rasmussen and Jensen (1974) have stratified human performance into three levels: skill-based,

rule-based, and knowledge-based. The three levels are defined in Figure 2.1.

Figure 2.1: Three levels of human performance: (Rasmussen & Jensen, 1974)

- Skill-based performance: cognitive pre-packed, structured thought patterns govern action
- Rule-based performance: cognitive, pre-packed, deterministic rules govern action
  [If x = y, then $x^1 = y^1$]
- Knowledge based performance: the solution is not pre-packed as the presenting situation is novel and thus requires a novel thought process for the action required

Humans inherently default to pre-packed solutions for actions, which increases the frequency of humans engaging in skill-based or rule-based performances. Of course this is not possible in a completely novel situation – which demands new and thus more demanding thought processes. While all of the above performance types could be used to carry out an action such as giving a range of drugs to a newly admitted patient, as the situation becomes more familiar, the need for knowledge-based performance diminishes.

Donald Norman (1988), through an analysis of human tasks, heuristics (or cognitive shortcuts), and error types, provided further order to the early theoretical base by delineating slips from memory lapses, and slips and lapses from mistakes. The first two are errors of action (or skill-based errors) and the third, errors of planning (rule or knowledge based errors). Figure 2.2 provides summary definitions of each, which are collectively described as unsafe acts (Reason 1997).

Figure 2.2: Errors of action and planning: summary definitions (modified from Reason 1990, p9)

- Slip: a potentially observable error which results from failure in the execution and/or storage stage of an action, regardless of the original plan's adequacy
- Lapse: predominantly related to memory failure, a less observable error which may only be apparent to the protagonist which also results from failure of the execution and/or storage stage of an action, regardless of the original plan's adequacy
- Mistake: a deficiency or failure in the judgemental or inferential processes involved in selecting an objective or means of achieving it, regardless of the outcome of any actions

2.2.2 Slips, lapses and mistakes: an analysis

A slip is observable (Institute of Medicine, 1999) and unintended. For example, the nurse who does not notice a 'nil by mouth' sign hanging above a patient's bed, and while delivering breakfast to patients who can eat and are on both sides of the fasted patient, then feeds them all. This type of slip - a capture error – is not uncommon in a busy environment, usually being associated with attention or perceptual deficits. Slips are essentially errors in the human automation process where there is no conscious control and the individual's normal routine is disturbed, even though the original mental plan is correct. Thus, one might be aware of an action but little attention is paid to it and completion is often swift (Sternberg, 2003). Originally novel processes become mastered through repetition and what were individual, discrete actions become translated into one coherent, integrated and *automatic* procedure (LaBerge & Samuels, 1974). Consequently, slips potentially imbue all routine behaviours. They also tend to take predictable forms (Norman 1981), and are more likely to be experienced by experts rather than novices (the latter being less able to automate), which has implications for the familiar lay (and sometimes professional) assumption about new staff being less reliable. Experts are further compromised by the mental storage of many more pre-programmed instructions (or schemata) than their junior colleagues.

There are three other common types of slip. Firstly, a description error is where the correct action is carried out but on the wrong subject/object, [e.g. the anaesthetist who provides a perfectly balanced general anaesthetic but on a patient who requires epidural anaesthesia]. Closely related to this is the associated activation error where, for example, a nurse might instantaneously but incorrectly silence an intra-venous alarm system when the (similar) trigger alarm ring is from a cardiac monitor. Finally, the loss of activation error is exemplified by the operating room assistant entering the anaesthetic room when s/he originally intended to go to the recovery room, and then once inside cannot remember why s/he is there until an environmental trigger stimulates their memory. This type of slip also intersects with a lapse. A lapse is simply forgetting something, for example the nurse knows full well that a patient requires analgesia at four hourly intervals but forgets to provide the analgesia at the time required.

A third category of error is a mistake - an action proceeds as planned but does not achieve its intended outcome as the plan was wrong. Mistakes are of two types: rule-based or knowledge-based (Reason 1990), a perspective again informed by the aforementioned taxonomy of human performance (Rasmussen & Jensen 1974). In a rule based mistake, the practitioner chooses the wrong pre-packaged solution to a familiar problem– be it owing to the wrong application of a correct rule, or simply the wrong rule. For example, a nurse expects a patient to administer his own insulin on time just as other patients have when asked to do so, but the patient does not and an omission error occurs. A knowledge-based mistake is where a faulty solution is applied to a novel situation; a junior doctor may decide he doesn't need to consult his formulary for a particular dose of a previously un-encountered antibiotic but he chooses the wrong dose through lack of information. The key element is the decision, he has made a judgement but it has not led to the desired outcome. Analysis of such decisions unearth particular cognitive biases such as availability bias (Kahneman & Tversky 1972) where the most easily remembered

facts – regardless of their objectivity, may be the most influential in decision-making. Mistakes are less well understood and can have more damaging consequences. These biases also impact on the way in which individuals report and analyse error (incident) reports, and are more fully considered under barriers to effective reporting (Section 2.7).

Reason's definition of error (Reason 1990), captures both errors of action and planning in failing to achieve an intended aim. Critically, the diversion of a person's attention can often lead to errors of action or planning. Specific schemata are disrupted and information processing becomes problematic. Various situational factors may also play a part; including unfamiliarity with the task, time pressures, poor signal/noise ratio, poor human/system interface, and or a designer/user mismatch (Vincent & Reason 1999, p51).

2.2.3 Violations

Reason has discussed rule (procedural or protocol) violations alongside active failures (Reason 2000, p768) – although, it is arguable as to whether they should be associated with errors at all as they are described as deliberate (or intentional) deviations from rules. Violations are thought to originate in psychosocial factors - chiefly personal motives (Ajzen, 1991), or organisational motives (Reason et al 2001) rather than cognitive factors (Reason 1990, Lawton & Parker 1998, Parker & Lawton 2006); and although deliberate, in relation to medical error, any consequent adverse effects are almost always unintended (Parker & Lawton, 2003). The propensity for humans to violate is probably increased by an unrealistic optimism about the relative risks (Radcliffe and Klein, 2002) more colloquially described as the 'it won't happen to me' phenomenon. However, the automaticity of thought previously discussed regarding slips may also lead to an unconscious violation such as a routine shortcut (Reason 1997, p210), and it is argued here that some practitioners might break a protocol but be ignorant of its existence, which would also be difficult to *strictly* classify as intended. There may be some uncertainty

concerning the status of violations in certain medical domains such as prescribing, for example Lesar et al (1997) concluded they cause little harm and are often re-interpreted correctly by nurses without clarification.

Four types of violation can be differentiated: routine, situational, exceptional and optimising (Lawton, 1998). The routine violation describes the regular, persistent breaking of a rule as part of standard, accepted practice. Situational and exceptional violations share common ground in that they arise from circumstantial demands when the protagonist finds it is difficult in his predicament to comply with the rule, or in the exceptional violation – there is either a novel problem or no suitable rule for resolution. Optimising violations occur when very experienced protagonists feel thy can do better by breaking a rule. Whereas the Health & Safety Executive (1999) have viewed all violations as requiring minimising (p16-18); Parker & Lawton (2006) in the context of medical error, appear to imply that some rules inadvertently promote violations. Indeed rule violations have also been described as an adaptive response, provoking learning (Amalberti et al 2006). Furthermore, the wide range of protocols, guidelines and policies in healthcare can make any consensus about what sort of behaviour equals a violation rather difficult (Parker & Lawton 2003).

2.3 Complexity of errors and organisations: multiple causes and multiple defences

For Rasmussen (1990), errors are generally described as part of a developmental or adaptive process, with individuals frequently resorting to cognitive shortcuts or heuristics to find the easiest way to complete a task. Yet despite some error types falling into recurrent patterns such as increased interruptions leading to slips and then omission errors (Alnutt, 1987); human errors are inherently unstable – largely because of the human component but also the often complex and dynamic context in which many humans operate (Rasmussen 1990, p454). It is then reasonable to

assume that errors cannot be totally eradicated by either system design or training – nor should they be – precisely because they can be developmental (Rasmussen, 1990, p457). Furthermore, Hollnagel and Amalberti (2001) have observed how human error is defined and that it is also dependent on group dynamics. Stressing the psycho-social ontology of error, Rasmussen (1997) has argued that humans can 'migrate' towards the margins of safety in order to undertake a given task by employing methods which may not be the most logical (or recommended), but reflect the social and or organisational norms that mould their practice.

The relationship between 'normal' accidents and modern technologies has been explored by the sociologist Charles Perrow through examining complex organisations. His much cited theory (Perrow 1984), is that 'tightly coupled' systems can present enormously difficult challenges in establishing accident or error causation; there is metaphorically, no crumple zone when a collision [or error] occurs, and no space for recovery. More importantly, Perrow proposes that complex systems actually facilitate organisational accidents [and errors], although this does *not* mean systems, by definition, are the cause of accidents. Rather they consist of paradoxically, in-depth, interdependent multi-faceted defences and can conceal errors from practitioners and their managers (Reason 1997). Additionally, if poorly designed - especially in hi-tech systems – they can trigger errors (Clarkson 2007) - which may be especially pertinent to processes such as electronic prescribing. Technological advancement can then produce gains but these may marginalise certain protective benefits (Perrow 1984, Vaughan 1996). Through his theoretical standpoint, Perrow (1984) was one of the first advocates of those at the operational end of an organisation.

Following major accident inquiries, the marine industry has clearly demonstrated that errors are rarely caused by single factors but the combination of several (Wagenaar & Groenwag, 1987), as more recently has the aviation industry, for example, the Kegworth aircrash (see Smith, 1999), and in healthcare, Wayne

Jowett (see Toft 2001). Slips, lapses, and mistakes are often elements in a 'concatenation' (a series of interconnected things, Oxford English Dictionary, 2001) of various cognitive, socio-cultural and situational factors (Reason 1990, Weick 1991, Perrow 1984, 1999), the latter of which can eventually create what Reason (1997) has described as 'latent conditions' (p 10). Furthermore, while slips, lapses, and mistakes can have a direct impact on intended actions, they are unlikely to have an enduring effect (Reason 1990, 1997). The NPSA's Patient Safety Observatory (NPSA 2005a, p56) has identified contributory factors in their retrospective analysis of incident reports and concluded that communication, education, and teamwork difficulties are apparent across all incident types.

Systems-based latent conditions on the other hand are often persistent, and as the word 'latent' suggests, they are rarely obvious (Turner 1978). Gaps in supervision or shortfalls in maintenance are typical examples but will nevertheless still, somewhat like mistakes, originate in human decisions but made at a *strategic* level (Reason 1990, p23). At this level, quite different influences might exist – stemming from group dynamics such as 'groupthink' (Janis 1972), but also from structural and cultural sources such as production pressures and bureaucratic accountability (Vaughan 1996). Certain upstream decisions can then lead to numerous error-producing factors downstream. Reason (1990) uses a range of metaphors to describe how systems failures ultimately manifest; the practitioner existing at the 'sharp end'– delivers a sometimes complex service but often amid a range of 'resident pathogens' each with opportunistic triggers (Reason 1990, p197-8) and awash with error traps. To successfully reduce the likelihood of sustaining losses while contending with a series of sometimes permeable and dynamic defences requires both individual wisdom and organisational resilience – related phenomena which will be discussed further under defences (Section 2.3.2). This perspective on the inherent weaknesses in complex organisations and their well intentioned but vulnerable in-depth defences is illustrated by Reason's Swiss Cheese model (see

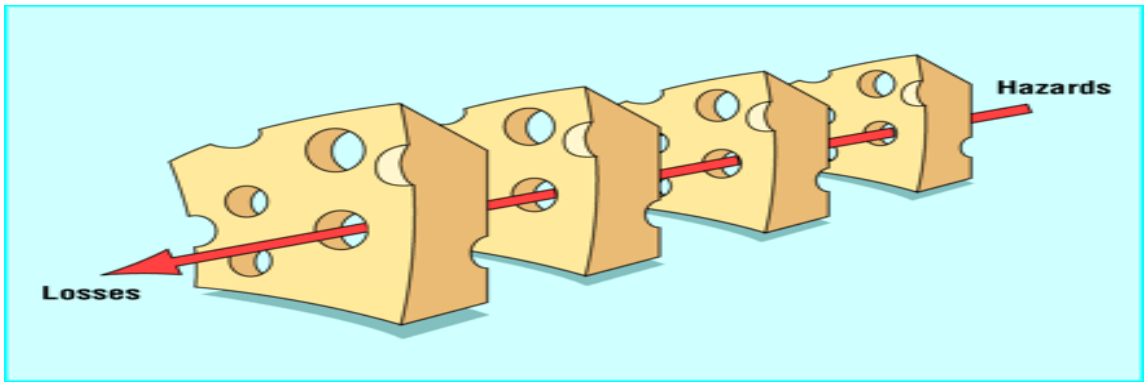
Figure 2.3). The holes in the Swiss cheese slices demonstrate the potentially porous nature of defences, be they owing to latent conditions or active failures. Importantly, the holes in the defences (or slices) will sometimes align to allow a hazard through, and although these defences are not always porous, the hazards are omnipresent. Furthermore, the model is designed to demonstrate that holes open, close, and align at random, and that systems should be the principle focus of error prevention and not individuals' actions. Despite the widespread use of this model to illustrate the relationship between causation and defence, it has been subjected to some criticism which will be recounted in the critique of error theory.

There are then, two approaches to error causation. Firstly, the person approach where there is an individual or singular focus on active failures and violations - stemming from a person(s) at the sharp end, and often evident in legal cases where compensation is being pursued (Runciman et al 2003). Secondly, there is the systems approach where causal factors are traced back into the system as a whole and remedial efforts are directed at the human response to a situation, but also its underpinning systems and associated defences. The latter is synonymous with what has been called the 'New Look' (Woods and Cook 2003). Importantly, these two approaches are not mutually exclusive – individual and system factors inevitably interact and combine to produce errors (Woods & Cook 2003) – an assumption upon which the Swiss cheese model is predicated but does not always make clear (see page 22)

While error types might fall into some recurrent patterns, predictability is hampered by concatenation but also in relation to medical errors – an inconclusive position on definition, and consequently causation. In a systematic review of 42 research papers, Hoff et al (2003) set out to identify the relationship between key independent system variables and medical error. Although the reasons were largely methodological, they concluded that very few empirical studies had robust operational definitions, theoretical frameworks and identifiable dependent variables.

They also proposed that identifiable variables such as a team approach and leadership were not proven to reduce errors in spite of their popularity in the literature. Nevertheless, the systems approach is broadly advocated across high risk industries and an energetic application to the context of complex organisations by Perrow (1984), together with key texts such as 'Man Made Disasters' (Turner 1978), and The Challenger Launch Decision (Vaughan 1996) have added the necessary weight. More recently patient safety literature by Reason (2000, 2004, 2005), Parker & Lawton (2002, 2003), Leape (2004), and Vincent (2001, 2006) have further served to raise its profile. Health care policy-makers have responded across the developed world [e.g. Institute of Medicine 1999, 2001; DoH 2000a, 2001; National Expert Advisory Group on Safety and Quality in Australian Health Care 1999]. It is also accepted at this level that a blame culture cannot advance either individual or organisational learning (DoH, 2000a).

Figure 2.3: The Swiss Cheese Model (Reason 1990, 1997) © Ashgate Publishing Ltd. Permission kindly granted to reproduce.



2.3.1 Blame: the individual as a sole cause

Attributing causation to systems is far more time-consuming than blaming an individual (Merry 1995, Reason, 2000) – individual blame is also likely to be less expensive than the inevitable systems overhaul if the latter is seen to be culpable. Additionally, any perceived performance deficit on the part of practitioners, especially if they are the last link in the error chain owing to a moment of inattention, is likely to receive far more attention than the less obvious, more deeply rooted latent failures. The risk of inappropriately attributing blame is considerable.

In fact there are three predisposing factors according to Runciman et al (2003): failing to acknowledge error is part of the human condition; a desire for compensation; and outcome bias, that is, the worse the degree of harm – the greater the risk of blame – independent of the likelihood of compensation (Caplan et al 1991). Caplan has also demonstrated that so called impartial experts are more likely to apportion blame when they are removed from the immediate events.

If practitioners are successful in their actions, little note is taken by onlookers. However, if unsuccessful - without the intervention of some unforeseeable event - they may find themselves, even if they have simply inherited an environment replete with systems deficiencies, in receipt of blame. The emphasis on inheritance rather than instigation is underpinned by Reason's belief that errors are consequences and not causes (Reason 1997, p126), although Reason attributes the original idea to Woods et al (1994). That it is easier to blame an individual but much harder to change individual behaviour compared to a system does not seem to deter those who seek individual blame. The inclination to individual blame appears especially prevalent in nursing. Compared to medicine and pharmacy, there is often a more intimate, individual patient relationship, and in drug error – the nurse is last in the professional line before the patient – thus potentially inheriting dispensing and prescribing errors, which can then, if undetected *by the nurse*, also become administration errors. A key rationale for blame is embedded in what Reason terms the 'illusion of free will' (Reason 1997, p127). This is where an organisation motivated to find an individual responsible for a given error, believes that the freedom of action s/he possesses means that the decision *they* have had the freedom to make incurs direct responsibility. Furthermore, from outside the organisation, the individual will be seen to not have got away with what s/he naturally deserved, known as the 'just world hypothesis' (Reason 2000 p768, after Lerner 1970). The obvious ramification of a blame culture is fear of authority, which in the context of this thesis is likely to manifest in a fear of error reporting.

Alternatively, a 'just culture' (Reason 1997, p205-13) is epitomised by individuals receiving positive attention for safety conscious behaviours including error reporting. There is clarity about what is acceptable and what is not; and individuals are only blamed if there is specific evidence of recklessness or negligence. The notion of a just culture can be paralleled with Westrum's notion of a 'generative culture' (Westrum 2004, p22) – encapsulating characteristics such as the promotion of an excellent information flow and individual empowerment throughout the organisation, and also undergirding the Manchester Patient Safety Framework or MaPSaF (2006). MaPSaF is a research-based tool for healthcare organisations which allows small or large groups to assess themselves against 10 dimensions of a patient safety culture where the most mature safety cultures see incident reporting as 'second nature' for all staff, including the reporting of near misses. The key characteristics of a high reliability organisation (Weick, 1987) also share common ground with the 'just culture' where there is a constant belief that the risk of errors is omnipresent and that a modus operandi of mutual appraisal and vigilance must be the natural default. Such cultural perspectives will be revisited in greater detail under Reporting Cultures (Section 2.7)

The casual reader may assume that Reason's drive for a just culture and his open antagonism of a blame culture may be indicative of a liberal stance on individual incompetence. Such a stance would be difficult to justify in a health service that has had to endure inquiries such as that led by Ian Kennedy concerning Paediatric Cardiac Surgery at the Bristol Royal Infirmary (DoH, 2001a). Drawing comparisons with jurisprudence, he isolates reckless or negligent individuals [or organisations] by claiming they possess inappropriate intentions as well as implementing incorrect acts. Perhaps Reason anticipated the potential charge of being soft on the incompetent and countered this by adding:

'Justice works in two ways. Severe sanctions for the few can protect the innocence of the many' (Reason 1997, p212)

2.3.2 Defences

With specific reference to health professionals, two related means of defence against error have been proposed: organisational resilience (Carthey et al 2001), and 'error wisdom' for combating errors at the sharp end (Reason 2004). Carthey et al (2001) have argued that organisations typically exist somewhere between two extremes of maximum resistance and maximum vulnerability to error – organisations must realistically move towards increased resistance (rather than error elimination) via three cultural drivers: institutional commitment, competence and cognisance. This should move the organisation towards a state of 'collective mindfulness' (p31).

Reason has contended that although risky and often complex, health care in comparison to other inherently risky types of work is a 'very personal business' (Reason 2004, p28), often lacking the moderation capacity of automated safeguards. Assessing mental preparedness is then the essence of error wisdom. The error-wise practitioner who reduces but knowingly does not entirely eliminate their propensity to err, will assess their own ability to undertake a given task, assess the environment, but also analyse the task and assess its error potential (Reason 2002, Reason 2004, p33).

The notion of defences, from an error theory perspective, has been strongly influenced by the argument for 'defence in depth' (Reason 1997, p8) yet mindful of the inevitability of error, its stochastic nature, and that defences in themselves are dynamic, Reason has described defences in depth as a 'mixed blessing' (p8), and Rasmussen – a 'fallacy' (Rasmussen 1993). Moreover, their greatest strength is then their greatest weakness – the sheer complexity of some defences may baffle the operator (or practitioner) or even conceal the error (Beatty 2006). With reference to the Swiss Cheese Model discussed earlier, Reason (1990, 1997) has described how both active failures and latent conditions will penetrate defences, as a result of local conditions and demands. Active failures can be invisible to the

organisation as individuals respond to conditions in a way they believe to be normal, for example, maintenance personnel on the Columbia Space Shuttle routinely and repeatedly brushed over scratches on an external fuel tank without reporting the fault so as to meet the launch deadline (United States Government, 2003). The relationship between neglected latent conditions and errors can translate into numerous, similar error types across an organisation and are insidious in their manifestation (Reason 1997, p54-5). Finally, the automation of defences herald new risks including chiefly: the boredom of the distanced operator, and his inability to stop closely coupled events in an error chain (Beatty 2006); and the increased risk taking of those sitting in an automated process who can (falsely) believe that automation provides a safety net or risk homeostasis (Adams, 1995). Such risks are germane to electronic prescribing – lauded as a key defence against drug errors (Bates et al 1998, 1999) - where new error types will undoubtedly emerge.

Finally, Leape (1994, p1856) has identified five specific 'mechanisms' that should be used to design out error: reduced reliance on memory, improved information access, error proofing, standardisation, and training. The mechanisms collectively respond to some of the inherent cognitive shortfalls above, that culminate in slips, lapses and mistakes. Certain innovations in contemporary healthcare have employed several of these mechanisms in unison, such as the development of protocols. From a related but different perspective, Amalberti et al (2005) have described five systemic barriers to 'ultrasafe healthcare'; in fact the barriers, like Leape's mechanisms have a common relationship, in this case it is at a socio-cultural level and about effective team working. The barriers can also be paraphrased as defences: limit the expectations and discretion of practitioners, reduce professional autonomy, [and consequently] shift from a hierarchical mindset to professional equivalence, system leadership, and simplification of professional rules and ways of working.

2.4 Critique of human error theory

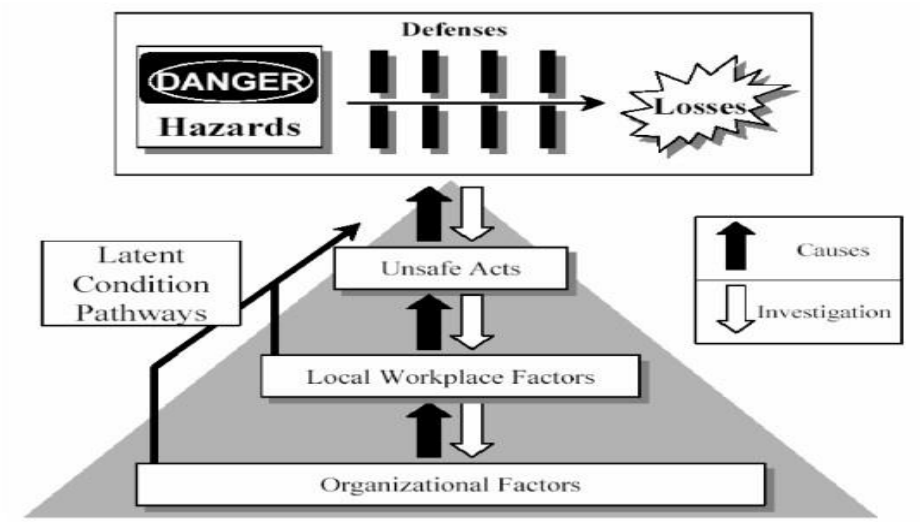
Although there appears to have been an unconditional adoption of human error theory by a number of researchers and policy makers – especially the work of Reason – the underpinning epistemology is open to criticism. Reason did perform several diary studies of error and followed this with studies of driving errors and violations, but many of the assumptions of his systems theory have gone untested, having been developed from evidence on the causes of errors. However and crucially, some of the error management tools that were developed using this approach, which have since been used by large organisations such as the Shell Oil Company, have not been empirically tested. As such there has not been a formal assessment of any comparative decrease in accident rates in organisations who use these tools versus those who do not (Lawton 2006, personal communication).

Kuzel et al (2003), have advocated a qualitative research approach to develop a greater understanding of the concept of medical errors and argued that Reason's definition of an error is not ideally fitted to healthcare, even though it has been adopted by several healthcare institutions, [e.g. Department of Health]. Mindful that Reason defines error as the 'failure of a planned action (or wrong plan) to be completed *as intended*', Kuzel et al (2003) argue that unintended (or poor) patient outcomes are not uncommon owing to the variable nature of illness, the treatment response and its limits. Second, they contend that even the best intentions can result in poor outcomes.

The conceptual clarity of Reason's Swiss cheese model has also been questioned following a survey of 159 volunteer health professionals at a patient quality conference. When asked about the utility and meaning of the Swiss Cheese model, they showed considerable inconsistency, a dominant theme being an overemphasis on latent conditions or systems factors to the neglect of active

failures. Although it was acknowledged that even Reason's own discussions of the model have changed over time (Perneger 2005). Perneger concludes by preferring the model of 1997, which explicitly shows the differing concepts of organisational and local workplace factors, as well as active failures (see Figure 2.4).

Figure 2.4 Stages in the development and investigation of an organisational accident (Reason 1997). © Ashgate Publishing Ltd. Permission kindly granted to reproduce.



What appears to be the most comprehensive appraisal of human error theory – particularly Reason's work, has been offered by Dekker (2006), a psychologist and trained pilot. First he has claimed that any error definition (and accompanying framework) is unavoidably subjective. Dekker has classified Reason's organisational accident model as epidemiological. As such he proposes that the user is likely to oversimplify causation perceiving it as linear and sequential, analogous with a unilateral trajectory of causation from boardroom to coalface; which as Perneger has pointed out, may be exacerbated by the one dimensional appearance of the Swiss cheese model. Although Dekker is explicit about the strengths of epidemiological models he proposes the alternative systematic model (Hollnagel & Woods 2006) as a much needed advance on the epidemiological model. The systematic model contends that error arises from a socio-technical context, it is intrinsically diverse (rather than linear) in its antecedents, and has roots in normal as well as abnormal systems and human behaviour. Dekker also adds that the various factors that converge to give rise to an error are jointly

sufficient. The systematic model is grounded in what is collectively known as the 'New Look' (Woods & Cook 2003), initially influenced by Erik Hollnagel (1983, 1993), it is also based on the work of Rasmussen (1990, 1990a, 1999) and Reason (1990, 1997) for its theoretical foundations. The essence of this theory is then built on a host of partly overlapping concepts which largely stem from cognitive and social psychology, but also organisational theory, and cognitive engineering (Woods and Cook, 2003).

Woods and Cook (2003) have discussed the key theoretical assumptions of the 'New Look' which are summarily paraphrased below, there is an acceptance that error is varied, inevitable, multi-factorial in causation, and can aid learning:

1. Error is not a human behaviour that always precedes failure, safety is not based on defending systems and stakeholders from erring humans
2. Error is not always an unreserved failure in itself
3. Error is not necessarily a deviation from accepted practice
4. Error research should accept errors as being diverse rather than uniform, much the same as human performance
5. How adverse events manifest themselves is more worthy of study than the adverse events themselves
6. Performance should be evaluated continuously, and against explicit standards, rather than simply after an error
7. Error arises from the interaction between individuals and systems and has psycho-social as well as technical components (Woods & Cook 2003, p3-8)

2.5 Defining drug/medication errors, adverse drug events, and error taxonomies

It has been demonstrated that drug error is one of the most common clinical errors in North American hospitals (Thomas, 2000); and that it is one of the most common causes of adverse events (Ghaleb et al, 2005), even though most have little

potential for harm (Bates 1999). In the UK between January 2005 and June 2006 the NPSA's National Learning and Reporting System demonstrated that medication incidents (within which drug errors are included) were the second most common reported incident after patient accidents, forming 8.3% of all reported incidents (NPSA 2007a). How a drug error is defined has quite radical epidemiological implications; too inclusive a definition can, for example, set inappropriately high standards (Ghaleb et al, 2005). In drug error research, it is essential that errors and their sub-categories are operationally defined before a study begins (Allan & Barker 1990). The most comprehensive definition of a drug error is probably that devised by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), it has also been adopted by the Department of Health and the NPSA (DoH, 2004, p20), and the National Audit Office (2005, p81):

'A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health professional, patient or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature: compounding; dispensing; distribution; administration; education, monitoring and use' NCCMERP, 1998: www.nccmerp.org/aboutMedErrors.html

The definition captures several important aspects of a medication error. First, the protagonist could be the health professional, patient or anyone obtaining a medication for consumption by themselves or another; that the error could arise from systems factors; and could occur anywhere along the medication pathway - from manufacture to the monitoring process post-administration. Furthermore, the statement that it is a 'preventable' event appropriately discounts unpredictable adverse drug reactions from being errors (essentially the equivalent of Reason's 'unforeseeable event'). However, the notion of intention is not made explicit, as it is in Reason's definition of an error, who has argued that intention and error are

inseparable (Reason, 1990, p5). Thus the NCCMERP definition does not isolate the protagonist's motive which in almost all cases will be the safe and effective delivery of a drug [to a patient or equivalent], and not a purposefully maleficent act – which could not be defined as an error. Additionally – whatever the definition, consistent, reproducible agreement on what is/is not a drug error is difficult to reproduce even between trained reviewers (Classen & Metzger 2003); a hazard of error research which is fully explored in the next chapter.

Unfortunately the plethora of terms used internationally in relation to medical and drug errors does not allow health professionals or researchers to negotiate an easy path through the field (Rubin et al 2003, Yu et al 2005). Although a drug error will culminate in either a near miss or adverse event, there are synonyms for both these terms. Yu et al (2005) found 25 in a search of 160 medication safety web sites, and also demonstrated using a scenario-assignment method with an inter-rater reliability assessment (κ), a considerable diversity in functional meaning. Such diversity is a threat to both specificity and sensitivity in literature reviewing.

The phenomenon of a 'near miss' has two dimensions (Bates 1999). A near miss is defined as 'a situation in which an action or omission, or a sequence of actions or omissions, which arises during care fails to develop further so there is no patient harm' (DoH 2000a, pxii). First, this may mean a pharmacist detects that a drug is prescribed via the wrong route and alerts the doctor before a prescription is handed to the nurse to administer the drug, but secondly and perhaps less obviously, the patient actually receives the wrong dose of an antibiotic but there is no effect on the patient whatsoever (DoH, 2004 p21). The term 'near miss' is sometimes absent from North American classifications systems, Morimoto alternatively using the term 'potential ADE' (Morimoto et al 2004, p306), under which they did *not* include 'minor errors that have little potential for harm', at odds with Bates (1999).

Perhaps the most expansive definition of an adverse event was provided in the

Harvard Medical Practice Study:

‘An injury caused by medical management (rather than the underlying disease) that prolonged the hospitalisation, produced a disability at the time of discharge, or both’ (Brennan et al, 1991, p370).

However, the character of the definition was influenced by the motivation and perspective of the study (discussed in more detail under the epidemiology of medical error, Chapter 3), which was medico-legal (Baker and Norton, 2002). A more concise definition is preferred here, which is taken from the same source as the near miss definition:

‘An event or omission during clinical care causing physical or psychological injury to a patient’ (DoH, 2000a, pxii).

Consequently an adverse drug event is:

‘An event or omission during the process of providing a drug to a patient that causes a physical or psychological injury’ (adapted from the previous definition of an adverse event, DoH, 2000).

The way in which an adverse event is defined has received critical attention. Walshe (2000) has identified that all definitions essentially have three characteristics: the negative or undesirable character of the event, the patient impact, and the cause (having emanated from the healthcare process whether though commission or omission). West (2000) has further stressed that the stem of adverse events, whether acts of omission or commission should receive equal weighting as although omissions appear to receive less attention – demonstrated by being reported less (Evans et al 2006), both can be equally potent threats to quality and patient harm. West (2000) concluded by proposing that adverse events are also conceptualised in terms of the health professional ethic but this focus may inadvertently contextualise all errors that become adverse events as some sort of

violation. Walshe (2000) has discussed adverse event definitions as part of a wider paper on measuring adverse events and as such some of his conclusions may have conceptual implications here. Walshe has cautioned that judging what is or is not an adverse event (and its severity) can in spite of any accompanying definitions be biased - in fact more detailed definitions may sacrifice validity for reliability, and that achieving good inter-rater reliability is rather elusive.

In conclusion, the diversity of definitions is an obstacle to a quick and easy classification of threats to patient safety, and is also a threat to the validity of reporting (Barach & Small 2000). Knowing that accurate and consistent definitions, (once tested), can lead to more reliable measurement (Walshe 2000), the NPSA have attempted to promote clarity and consistency, but even they seem to have shifted from a focus on errors, near misses, adverse events (See DoH, 2000a) and medication errors (See DoH, 2004) to the broader based 'patient safety incidents' (NPSA, 2004) and very recently 'medication incidents' (NPSA, 2007a). A patient safety incident is defined as 'any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS funded healthcare' (NPSA, 2004, 2005). In relation to this study, a drug or medication error will be defined according to the definition offered by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP, 1998), however as discussed above, its comprehensiveness is likely to make it a 'catch-all' term (Morimoto et al 2004, p.306). Lastly, it is conceptually apparent that errors will either result in near misses or adverse events, but each is equally worthy of reporting (Barach & Small 2000). While their pattern of causation may be the same, it is the presence or absence of a recovery mechanism that alters their outcome (Barach et al 1999) and this can be a valuable source of learning, especially from an accumulated mass of reports.

2.5.1 Drug errors: the purpose and nature of taxonomies

Having described the problems with defining error, it is then unsurprising that there

is also a lack of clarity in medical error taxonomies, in fact the situation has recently been referred to as 'muddled' (Vincent 2006, p85). Developing such a taxonomy is not an easy exercise (Avery, 2003), but even when developed, inaccuracies and varied perceptions will lead to problematic implications. The components of a valid and reliable error taxonomy are now described, and second, the risks of not having a taxonomy.

An accurate taxonomy or *whole* classification system will allow comparisons to be made between errors so as to ultimately tailor interventions that can detect, manage and even prevent such errors recurring (Runciman et al 1998). Patient safety taxonomies frequently have three grouped categories: event type, causation, and risk (WHO, 2005). In the context of incident reporting, Runciman et al (1998) have also argued for the inclusion of contributory factors which form a sequential causation index for the Australian Incident Monitoring System (AIMS). A particular strength of the Australian system is its empirical base (Webb et al, 1993), but also, by drawing on the work of Norman (1988) concerning natural mapping, its theoretical underpinning.

In recounting the development of a multi-level taxonomy of patient safety in general practice, Kostopoulou (2006) has highlighted the advantages of an accurate classification system, and clearly supported Runciman's claims having cautioned that an absence of theoretical underpinning can lead to a range of categories that are neither mutually exclusive nor exhaustive (Kostopoulou 2006, p486). This threatens the very comparative processes and error prevention that Runciman has envisaged. Kostopoulou has argued that many patient safety classification systems are simply based on tasks, [e.g. drug administration], going on to list error types and causes which she asserts, without any theories of cognition, will only identify the visible elements of a given incident.

While Kostopoulou (2006) has acknowledged the importance of cognition to

understanding error, she has also demanded that taxonomies include systems factors and how they might interact with individual factors, emphasising the notion of concatenation that is so prevalent in Reason's work. This then presents a new problem. The need for comprehensiveness and sophistication may result in a taxonomy that is extremely difficult for practitioners, (or incident reporters) to understand. Indeed Kostopoulou has critiqued other taxonomies such as that of Zhang et al (2004) which she sees as unnecessary complex, despite a lack of focus on latent conditions. Drawing on data from attendance at meetings, staff interviews and task analysis, but principally the review of 77 incident reports, Kostopoulou (2006) devised a taxonomy consisting of three tiers: active failures; immediate causes (for example: either internal such as stress, or external such as poor stock control); and latent conditions. Interestingly, Kostopoulou found that sourcing most of her data from error reports was a problem due to their limited information.

Both Zhang (2004) and Kostopoulou (2006) highlight the lack of theoretical validity in the National Coordinating Council for Medication Errors and Prevention (NCCMERP) taxonomy. Errors here are classified according to task, type and cause - drawing on their external manifestation without considering any cognitive processes, thereby limiting an understanding of the various interactive mechanisms inherent in error. Nevertheless, the NCCMERP taxonomy, as it has been adopted by both the DoH and NPSA and is appropriately comprehensive, provides the operational definition for drug error in this study.

Secondly, not providing access to a definitive taxonomy can lead to staff internalising their own, which is not ideal, for example, a 'close call' – yet another synonym for a near miss can semantically, suggest to staff that the related event was more a cause for celebration than a reason for inquiry (Weick & Sutcliffe, 2001). Tamuz et al (2004) looked in detail at how a formal and informal classification of drug errors would influence the reporting process and any

associated learning. From eighty six qualitative interviews with hospital staff – mostly pharmacists, it was found that how an incident was conceptualised by staff could lead to under-reporting, limited analysis and reduced learning. Staff whose personal or professional group definition [of a reportable incident] did not fit with a drug error failed to report it, such as when a doctor made a prescribing error but this was detected by the pharmacist before being dispensed. Interestingly, this was perceived as a pharmacist 'intervention' rather than a reportable near miss. This shares common ground with an earlier qualitative study of Australian nurses' essentially informal classification of drug errors which through interviews, but also observation and incident report analysis, demonstrated that clinical nurses made particular decisions about error classification such as 'if everyone knows about an error ……and if you can put it right, it isn't an error' (Baker, 1997).

Finally, it is apparent that both error definitions and taxonomies remain problematic, and even though Runciman et al have moved that the inclusion of contributory factors is essential, the diversity of taxonomies as well as definitions seems to create some obfuscation. This is likely to have led to the World Health Organisation proposing a single, theoretically underpinned taxonomy of patient safety (WHO, 2006). They advocate the following attributes in an ideal taxonomy: the terms chosen are transferable across multiple healthcare settings; information collected should identify and analyse causation and preventative strategies; the identified contributory factors should illuminate systems failures; and the information should provide a stout public health, aggregated data base.

2.6 Epidemiology of drug errors

2.6.1 Epidemiology of medical error

It is logical and complementary to first consider the general epidemiology of medical error before the specific epidemiology of drug errors. Over 50 years ago, Moser urged professionals to seek a better understanding of those diseases that

appeared to have emerged from the effects of treatment (Moser 1956). Less than 10 years later the term 'untoward episodes' was used to describe the problem as experienced by 20% of all admissions to the medical wards of an acute hospital in North America (Schimmel 1964). This was followed by an evaluation of the effects of physician's performance on their patients (Sanazaro et al 1974). Steel et al (1981) monitored all admissions to a medical unit at an American teaching hospital. They used a 27 item data extraction tool to monitor a range of biographical and clinical data which included complications defined by their severity and impact. Their analysis demonstrated that of the interventions that led to iatrogenic complications, drugs were the most common cause. These early studies notably concentrated on iatrogenesis, but made little discrimination of preventable events (or errors), from non-preventable.

The Harvard Medical Practice Study (HMPS), conducted by Brennan and Leape, was published in two consecutive papers (Brennan et al 1991, Leape et al 1991). It is described in some detail here as its methodology informed a substantial series of large scale epidemiological studies of preventable events. Furthermore, its findings stimulated the first influential policy document centred on medical error in the USA (Kohn et al 1999); it also identified adverse drug events as the second most common type of adverse event. The HMPS employed case note review, but unlike its often ignored predecessor (California Medical Association, 1977) the sample was random rather than convenience. However, in common with the Californian study, error was conceptualised in terms of its potential [outcome] as a financially compensatable event. Just over 30,000 randomly selected hospital admissions were selected from 51 randomly selected acute hospitals in New York State in 1984. The weighted sample of 31,429 was selected from a population of 2,671,863 patients. Although the principle objective had been to identify injuries that would become part of the tort process, the study gathered sufficient data on the incidence and nature of adverse events to demonstrate key factors which might increase the

likelihood of such an event. Adverse events that were thought to have occurred pre-admission were also included to compensate for events caused during admission but only uncovered post discharge. The screening process was in two stages: trained nurses screened in the first and physicians in the second. A numeric scale was used to record researcher's confidence in identifying an adverse event and any apparent disability. Finally any negligence was also subject to scale measurement. Independent review resolved differences between physicians, 1% of records were re-reviewed using a blank form (blinding the original review), and Kappa used to compare agreement. Weighted percentages and population projections were calculated and significant differences in rates tested with the Wald statistic; crude rates of adverse events were split into 5 age groups and standardised to control for the risk that a particular diagnosis would result in an event. Diagnosis related groups (DRGs) were also scored on a scale of 1-6 to assess the likelihood of association with an adverse event. The denominator for the percentage of negligent cases was the number of adverse events which also acted as a control for complexity of care. The state wide incidence of adverse events was calculated to be 3.7% (CI 3.2 to 4.2), 27.6% of these having been judged as due to negligence. The impact of most adverse events was seen as minor, [i.e. complete recovery in 1 month], although patients and their families would be less likely to judge such an impact as minor. A total of 6.5% of patients suffered a permanent disability and 13.6% died - negligence was found to be more common in severe events. The adverse event rate was found to increase with age, especially in those over 64 years. The rate also varied across diagnosis related groups. The emergency room was the most common location for preventable events. Importantly, the data were reanalysed which established that 69.6% of the adverse events were judged as preventable (Leape et al 1993) – thereby also illuminating the proportion of events that may have stemmed from error (Weingart et al 2000). Furthermore, the leading cause of medical injury stemmed from drug therapy. However, the limitations of the study are a reflection of the issues

discussed earlier, namely: incompleteness of case notes; low inter-rater reliability in agreement processes – especially in deciding negligence; and the time consuming and costly nature of data collection. Generalisability of the findings has also been questioned on the premise that Brennan et al (1990) underestimated adverse event rates as the proportion of patients affected were simply multiplied over the total patient population in the USA to produce a national rate. The HMPS findings were also arguably skewed by:

1. Adverse events having to reach a specific level of harm
2. Case note review being the only source of data
3. The standard of two physician review (and agreement) being above the one expert witness required for a legal claim (Andrews et al 1997)

Moreover, measuring medical errors by outcome (as adverse events) excludes those errors that lead to near misses (Weingart et al 2000).

The Utah & Colorado study (Thomas et al 2000), although carried out in the same year but published after the Quality in Australian Healthcare study or QAHS (Wilson et al 1995) used the same operational definitions and methods as HMPS but with just under half the sample size and from only 28 hospitals. The results were remarkably similar: adverse events occurred in 2.9% of hospitalisations, with just over half judged as preventable, and again a high proportion of events were seen to be due to negligence (approximately 30%). Also in common with the HMPS, the emergency room was found to be the most common site for negligent events. In Australia, Wilson et al (1995) used very similar methods with a comparable sampling frame to Thomas et al (2000) but their goal was to inform quality improvement methods, consequently evidence of negligence was not mandatory, the focus was instead preventability of adverse events. The change in orientation produced a much higher rate of adverse events: 16.6% of hospital admissions, with 51% being judged as preventable. The higher rate was also thought indicate better

case note documentation. Adverse drug events were the fourth most common event (10.8%). The Australians also provided a ranking order of causative factors: 34.6% judged as due to technical performance, 15.8% due to failure to act on information, 11.8% failure to request/arrange a procedure, and 10.9% falling into the rather diffuse category of 'lack of care'. The first three factors illustrate that chart review inclines towards individual rather than systems failures (Baker 2004). The QAHS also demonstrated that acts of omission were twice as likely to be implicated in adverse events as acts of commission.

Further HMPS replication studies have been carried in the UK (Vincent et al 2001), Denmark (Schioler 2001), New Zealand (Davis et al 2002), and Canada (Baker et al 2004). Vincent et al reviewed a much smaller number of randomly selected case notes (n=1014), from just two hospital sites across four specialities, the authors adding that the case mix did not represent UK hospital practice. Appropriately described as a pilot, it was found that 10.8% of admissions experienced an adverse event, and that half of these would have been preventable. Schioler et al and Davis et al generated similar proportions of adverse events. Schioler et al also described their study as a pilot, suggesting further research on high risk groups and interventions. Davis et al added that while their study was based on a representative sample for their host country, the findings must be interpreted with caution due to the inevitable subjectivity in reviewers' judgements. Baker et al (2004) stressed that their adverse event rate was smaller than almost all of the other epidemiological studies excepting the HMPS - where the predominant focus was on evidence of negligence. This study was also able to demonstrate the difference between small, local hospitals and larger teaching hospitals, postulating that complexity of care and a related, increased risk of miscommunication accounted for the higher adverse event rate in teaching hospitals. The sample sizes and principle findings of these and the other incidence studies discussed above are shown in table 2.1. The Canadian study also demonstrated a notably

different proportion of preventable adverse events.

Table: 2.1 Studies of adverse events using case note review

Authors (Study country)	Sample size (number of records)	% of admissions that experienced adverse events	% of adverse events that resulted in permanent harm / death	% of adverse events judged to be preventable
Brennan et al 1991 (USA)	31,429	3.7%	6.5% / 13.6%	69.6%
Wilson et al 1995 (Australia)	14,179	16.6% (13%) [1]	13.7% / 4.9%	51%
Thomas et al 2000 (USA)	14,052	2.9%	8.4% / 6.6%	51%
Schioler et al 2001 (Denmark)	1,097	9%	2.7% / NA	40.4%
Vincent et al 2001 (UK)	1,014	10.8%	6% / 8%	48%
Davis et al (2002) New Zealand	6,579	12.9%	10.2% / 4.5%	N/A
Baker et al 2004 (Canada)	3,745	7.5%	5.2% / 15.9% [2]	2.8%

[1] adjusted to 13% following application of HMPS criteria.
[2] there were 46 (15.9%) adverse events that resulted in death but in 40 patients, when the figures were adjusted for the sampling strategy it was estimated that death would be associated with 1.6% of hospitalisations in Canada.

Away from the exclusive use of case note review, other methods include: case note review with prompted self reports, electronic analysis, observation and post-mortem examination. The North American study discussed in relation to its sensitivity (Andrews et al 1997) suggested a significant 17.7% of patients experienced a *serious* adverse event, and 45% of patients an adverse event. Close examination of the method however, showed a very different definition of adverse event which did not mention patient harm, indeed it appeared contradictory to most accepted understandings: 'situations in which an inappropriate decision was made when, at the time, an appropriate alternative could have been chosen' (p310). Of interest here is that the fine detail gathered demonstrated that 15.6% of the events had

causes emanating from inter-professional communication within local or hospital-wide teams. Furthermore, just over 50% of the cases were judged to have had multiple causes.

Post mortem studies have been reported from Spain and Norway. Bombi et al (2003) demonstrated discrepancies between diagnosis and post mortem cause of death. In Norway, Ebbeson et al (2001) reviewed a series of 732 drug related deaths over 2 years (5.2% of all unit admissions) in the Department of Internal Medicine. Through comparison of case notes with autopsy reports, they found that 133 deaths (18.2%) were directly (64) associated or indirectly (69) associated with 1 or more drugs. Again, elderly patients with multi-pathologies and receiving cardio-vascular, anti-thrombotic & sympathetic drugs were especially affected.

The principle studies have been carried out in university teaching hospitals which threatens the generalizability of results to smaller, non-referral hospitals (Weingart et al 2000), and of course primary care. The overview given here has largely focussed on incidence and type but some studies have also focussed on causation. The incidence and type of drug errors are now detailed, however, those studies which have addressed causation *specific to drug errors* are, because of the research question, discussed and appraised in the systematic review (Chapter 3).

2.6.2 Epidemiology of drug errors and adverse drug events

As discussed above, the HMPS and other large scale epidemiological studies (Malpass et al 1999a, Thomas et al 2000) found drug errors to be a common source of adverse events – the latter estimating that they formed about 20% of the total number identified. As demonstrated, it is one of the most common causes of adverse events (Ghaleb et al, 2005), but most have little potential for harm (Bates 1999). Although this is a valuable observation it should not diminish the importance of drug errors as one indicator of an organisation's level of safety. While it is difficult to be confident about comparisons between secondary and

primary care, Phillips et al (1998) in a 10 year comparative analysis of medication errors in out- patients and in-patients found that the in-patient group had a much increased mortality rate. Yet again however, a spurious definition of error included all accidental poisonings of which many are patient-initiated.

Reports of the incidence of drug errors – by whatever method, are likely to be underestimates as many go undetected (Corrigan 2001, Classen and Metzger 2003). As has been proven elsewhere, data from incident reports are especially prone to this phenomenon (Malpass et al 1999a). Due to the nature of this study's objectives, the problems with reporting data are discussed in more detail under methodological issues(Section 2.9.2), and revisited in the systematic review of drug error reporting schemes.

2.6.2.1 Incidence of drug errors

The measurement of drug errors has been described as a conundrum (Classen and Metzger 2003). It is generally hampered by the same methodological snags as medical error research, and as these have been discussed, they will not be revisited in any detail. Also, in common with studies of medical error, observation has been suggested as the most reliable method of detection (Allen & Barker 1990, Dean & Barber 2001), although this seems largely applicable to administration errors. Using a range of relevant papers retrieved from the systematic review of contributory factors in drug errors and the reference lists therein, the data on the incidence of drug errors are presented in Appendix item 2. Heedful of the methodological issues discussed earlier, incidence is reported alongside authors' definitions of error or adverse event, their methods, and the sample size/setting from which the data were collected; all having been described as influential in affecting the error rate (Ghaleb & Wong 2006). The denominator is also tabulated to illustrate its variance, which again critically influences the related findings (Franklin 2005). The largest dedicated studies were those carried out in the USA by the ADE Prevention Group (Bates et al 1995a, Leape et al 1995).

Allen & Barker (1990) published one of the earliest methodological papers on drug error research, concluding that a consistent operational definition is necessary. Judgements on what is/is not an error also requires independent validation, although reliability checks seem to be rather more focussed on adverse events. Allen and Barker suggested from an earlier analysis of 'findings to date' (p556), that the drug error rate is about one per patient per day (Barker et al 1984) but somewhat surprisingly excluded wrong time errors which can wreak havoc with specific patient groups such as those with Parkinson's disease (Parkinson's Disease Society 2006). Allen and Barker's exclusion ironically proves their own point - that error rates will vary according to the definition chosen, further illustrated by the WHO definition of an adverse drug event which includes adverse drug reactions (Classen et al, 1991; Rozich et al 2003).

Allen & Barker also added that the detection of drug errors through incident reporting is fraught with difficulty as it rests on the reporter being error aware (you need to know one to report one), and surmounting the various barriers discussed earlier. As in medical error research, it is unsurprising the analysis of report data is again less commonly used to establish incidence. Where reports have been reviewed, they have sometimes been purposely solicited, presumably to increase the reporting rate. Common methods of detection include chart review, sometimes accompanied by more extensive case note review; and observation which is used in both disguised and non-disguised forms. Flynn et al (2002) compared three methods of detection and found 300 errors out of 2556 doses observed, compared to just 17 detected through chart review, and 1 by incident report. Chart review is the most common method, but its success is also dependent on the stage(s) of drug delivery being studied, and would not be especially useful in discovering administration errors. Adverse events are of course easier to identify than errors, being defined by patient harm. Interestingly, as they are far smaller in comparative incidence - especially severe adverse events, there is sometimes a perverse

perception of a low rate of harm (Classen et al, 1991).

Like the benchmark studies of medical error, the location for most of the studies was the teaching hospital. It can also be seen that where data was collected from a range of clinical specialties that a comparatively higher error rate existed in intensive care units (Wilson et al, 1998). The relatively high poly pharmacy (Naylor 2002), and more closely coupled work undoubtedly provides more error opportunities. Although Naylor may have overlooked socio-cultural factors that could have provided a greater inclination to report errors, Wilson's work having been based on *reported* error rates.

Although single stage studies dominate, several studies have also discriminated between error rates by comparing the different stages of prescribing, dispensing or administration errors. It would appear from some studies that preventable and potential ADEs are most likely to stem from the prescribing (or ordering) stage rather than administration, although the difference can be small (Bates et al 1995a, Allen La Pointe et al 2003). The rates again vary according to the denominator, the most common denominator being errors per dose, or prescription item. Errors per opportunity for error, is used for observational studies. There are few studies of dispensing errors.

More recent studies show that drug errors are also more apparent at interfaces of care (Rozich and Resar 2001). It is apparent that a considerable volume of prescribing errors occur at admission rather than any other time, whether prescribed electronically or not (Pronovost et al 2003, Cantrill 2006). A small study by Vira et al (2006) based on 60 randomly selected patients found that 60% of patients at admission and discharge experienced at least one unintended error, and 18% of these were clinically important.

It has also been suggested that higher patient turnover in one unit compared to another might contribute to a higher drug error rate (Taxis et al 1999). Despite a

plethora of studies, very few have collected data from patients on drug errors, which as Naylor (2002, p36) has suggested, could be an important additional source of data. General adverse event or outcome studies also provide less data on process – on which there is generally less information. It is agreed here that measurement remains a conundrum but also due to the plethora of methods. Many of the incidence papers cited in Appendix item 2 also provide information on causation, however, not all recorded detail of error type and commonest drug type involved. Those that did are discussed below.

2.6.2.2 Error types and common drugs involved

The NCCMERP (1998) taxonomy encourages practitioners to classify drug errors by type. Many authors have identified the most common error types and the most common drug types involved. Bates et al (1995b) have indicated that the most common error type is a dosing error, supporting their view with evidence from 6 studies (p203). The finding was replicated later the same year in one of the largest studies undertaken, having reviewed 4031 admissions (Bates et al 1995a) across ordering and administration stages; and in two large prescribing error studies (Lesar et al, 1990, 1997). Dosing errors were also most common in four Australian studies (Runciman et al, 2003). Another leading error type is drug omission (Ridge et al 1995, Ho et al 1997, Dobrzanski et al 2002), alongside wrong time errors, the latter being more prevalent in drug administration error studies (Hartley & Dhillon 1998, Barker et al 2002, Tissot et al 2003, Prot et al 2005). Interestingly, some studies have excluded wrong time errors.

There is however, some terminological confusion about the description and categorisation of dosing errors, for example Ross et al (2000) listed incorrect strength and incorrect dose as separate categories. There is also a lack of fine grain differentiation between overdose, underdose and extra dose. The frequency of error types is also influenced by clinical speciality, the obvious being the large number of dosing errors in paediatric settings.

The most common drugs involved in ADEs are not always identified but analgesics (Classen et al 1991, Bates et al 1995a) have figured prominently, and in errors – antibiotics (Lesar et al, 1990, 1997; Kaushal 2001). Runciman et al (2003) in their systematic review of ADEs and drug errors have identified anticoagulants, NSAIDs and cardiovascular drugs as being the most commonly implicated, but also anti-neoplastics, analgesics and antibiotics. The risks of NSAIDs, anticoagulants, and analgesics is further stressed by Naylor (2002) who had pointed out that they formed over half of the adult drug related deaths in a Medical Defence Union study (Dalby 2001). There also appears to be a relationship between particular error types and the drugs involved, for example, dosing errors and NSAIDs (Naylor 2002). There may even be a relationship between the stage at which an error occurs - such as prescribing, and the most common contributory factor for medical staff – limited knowledge (Leape et al 1995). Although single factors result in many error types and a single type can stem from many factors (Leape et al 1995), it would seem that little published evidence exists about the interplay or concatenation of factors.

2.7 Reporting systems for errors, near misses and adverse events

2.7.1 Definition and purpose

Incident reporting is essentially a formal means of gathering information about incidents in the workplace. The New Oxford English Dictionary (2001) offers several definitive descriptions which accentuate that an event must bear some *significance* for it to be an incident, [e.g. it is dangerous, hostile, violent, exciting]. If incident reporting is the communication of safety information, then an incident should be an event that is significant to the safety of the host organisation, those to whom it provides a service, or its staff. Reason has summarised the potential advantages of incident reporting which also serve as rationales, but notably in the

context of near misses:

1. In common with vaccination, reporting can mobilise a system's defences against more serious events [usually] without damage to the host
2. Reporting can provide qualitative data that can inform the trajectory of an incident
3. [If near misses are reported which would increase the sample size] reporting schemes can also provide quantitative data
4. Reporting serves as an organisational *aide memoire* about the ever present risk of errors, although this relies on an active dissemination process (Reason 1997, p119)

Reason has also made clear his opinion on near miss reporting which is applicable to all reporting systems. He believes it is valuable, even though they may be hampered by their reliance on a willingness to report and the ability of the reporter to provide a detailed account of the various contributory factors – both upstream and downstream. Indeed it appears that a host of problems conspire to affect the efficacy and effectiveness of reporting. However, before discussing reporting in healthcare and the reporting of drug errors in detail, some attention will be given to reporting outside healthcare which will ultimately provide a rough estimate of the comparative maturity of healthcare reporting, as well as a broader insight into the general principles. In common with Barach and Small's clinical review of reporting systems (2000), two other high risk occupational domains are considered: aviation and nuclear power.

2.7.2 Incident reporting: the broader occupational picture

Many incident reporting systems outside of healthcare appear relatively mature, but they still have problems and as will be seen, these problems are not dissimilar to those in healthcare; their achievements are also instructive. The high risk domains of the aviation, aerospace, nuclear power, and petro-chemical industries have well established systems. There are generally two types: mandatory and voluntary

(Vincent 2006), although Vincent does not clarify the distinction other than stating that mandatory systems are compulsory (p.61). Mandatory reporting systems can be compulsory through the existence of an administrative mandate, or legislation (such as the New York State system discussed below). They may also be compulsory by virtue of their technological status as automatic monitoring systems such as the black box in aviation, and the Signals Passed at Danger (SPAD) mechanism in the railway industry. Voluntary systems are not underpinned by any legal or administrative requirement to report, or any technical monitoring. However, whether voluntary or mandatory, if there is no process of automatic monitoring, it is likely that the [human] reporter will ultimately render them both voluntary as s/he must be willing to report in order to submit (Billings 1998a, Clarke 1998). A more robust distinction is that between a confidential and anonymous system. Confidential systems ostensibly protect the identity of the reporter, even though their name is submitted; anonymous systems do not require the identity of the reporter. However, Tamuz (1994), has acknowledged that if organisational processes allow management to identify a worker, the guarantee of confidentiality in the so called confidential system is lost. Furthermore, there is a tension between an organisation's declaration of an open culture - where workers openly discuss errors - and the belief that reporting should be confidential which can imply the need for protection from management (Berman & Collier 1996). Alternatively, although at odds with Reason's generic concern about the willingness to report, it may follow that reporters who submit to a voluntary system may be more motivated to seek a resolution to their reported incident.

Barach and Small (2000) carried out a literature search of non-medical reporting systems which identified twelve systems, the information for which was supplemented by interviews with their respective safety consultants. Seven systems were managed and mandated by central government, ten were confidential and the remaining two were anonymous. The systems were

differentiated by their methods of defining, counting and tracking adverse events, but commonality lay in the high value given to reporting near misses. Citing supportive literature, Barach and Small (p760) proposed several advantages in reporting near misses compared to adverse events, of which several were different to Reason's list above:

1. They allow an analysis of commonalities between small scale 'failures'
2. Knowledge of recovery can enhance preventative strategies and diminish any focus on blame
3. There is no concern about organisational or individual indemnity
4. They allow insights into hindsight bias

Feedback to reporters was also seen as a priority, but the authors also added that quality (of data and feedback) hinged on confidentiality, independent data collection and analysis – the latter by experts, as well as ease of reporting and strong leadership. In short, reporters trust a system where they experience receiving informative feedback as well as giving information, and witness local improvements stemming from the act of reporting itself.

2.7.2.1 Aviation reporting systems

These reporting systems have been independently developed by either private companies, the government bodies which regulate them, or charitable foundations. The two principle reporting schemes for British airlines have been the British Airways Safety Information System (BASIS) and more recently, the Confidential Human Factors Reporting System (CHIRP). These systems also strongly promulgate the reporting of near misses as part of a human factors approach to safety. The aviation industry has recognised that a voluntary incident reporting system is an important means of reducing serious accidents, and critically, operates within a quite different culture imbued with values that have been moulded through the often drastic consequences of some errors – for staff as well as

passengers. Records show that more Royal Air Force pilots were killed during the second World War by technical failures (including human error) than by the enemy, and it is a salutary reminder to all pilots that a serious incident is very likely to result in their death as well as, often before the persons to which they provide a service (Butler 2002). In spite of the Federal Aviation Administration having developed a confidential incident reporting system over 30 years ago, which favoured learning over blame (Busse & Wright 2000), less than 20 years ago British Airways had amassed a hefty volume of largely meaningless paper-based reports which demonstrated that reporting occurred but analysis had not (DoH 2000a). Failing to learn is critical, especially from near misses, as the equivalent of an adverse event (a plane crash) may yield very little owing to the wholesale loss of evidence and potential witnesses, as well as the fact that airline crashes are increasingly rare in the developed world. Thus, specific airlines like British Airways instigated systems that reporters could trust, now subscribing to a confidential and anonymous reporting system (CHIRP) managed by an independent charity. Based upon human factors, the system underpinned by the premise that it is *not* normal to take disciplinary action when an error is reported - unless there is proven recklessness (Reason 1997), but that failure to report a significant incident necessitates full exposure to disciplinary action.

In contrast to the usual status of the risk manager in the NHS, the equivalent post-holder in the aviation industry appears to exert far more influence. Using ThomsonFly as an example, the Flight Safety Manager – who receives all incident reports, also chairs all key organisational meetings dedicated to risk management. These occur approximately every ten days and both the Chief Pilot and Chief Training Pilot are present. Feedback is via an intranet news desk and any crew member may request feedback at any time (Last 2004, Personal Communication). Finally, in most airlines the concept of crew resource management (CRM) now governs ways of working, including reporting. It is also known that pilots and crew

have a history of difficulty communicating with each other, just over 65% of aviation accidents between 1959 and 1989 were attributed to the flight crews (Helmreich & Foushee 1993) which clearly necessitated change. CRM is a particular way of working informed by the social sciences, psychology, and engineering – its aims being to optimise performance and reduce human error (Helmreich & Foushee 1993). It is critically focused on the quality of interactions and openness between crew members, for example, avoiding distractions and admitting mistakes (See Appendix item 1 Pilot Skills List, 2005). It is in this socio-cultural context that incident reporting has become integrated into standard operations, and as has been argued elsewhere a suitable culture is essential for initiatives such as reporting to thrive (Carthey, 2001). Indeed aviation reporting systems in tandem with CRM and improved technology are credited with the significant risk reduction in flying (Institute of Medicine, 1999). The principles of CRM have been used specifically to improve reporting rates at a British acute hospital trust (Higton 2006).

2.7.2.2 Nuclear Power

The history of nuclear accidents demonstrates that whatever the stakes, a reporting culture is not a given.

Grigori Medvedev – a senior Russian Energy Ministry official at the time, claimed that at Chernobyl:

'.....mishaps were never publicised, nobody knew about them, nobody could learn from them..... for 35 years people didn't notify each other about accidents and nobody applied the experience of such accidents to their work' (Medvedev 1989, p39).

However, more recently (in the developed world at least) Barach and Small (2000) found stronger safety cultures where near miss reporting was valued. While the aviation industry can focus its workforce's minds on reporting through the potentially fatal consequences for all on board, the implications of any nuclear

reactor failure would potentially impact on a much larger population, over a protracted period, and with widespread political as well as environmental repercussions. The IRS (Incident Reporting System) is currently the principle reporting scheme, created in 2006, and participated in by 31 countries who freely exchange safety information. It is jointly operated by the International Atomic Energy Authority (IAEA) and the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development (OECD/NEA). Reporters are protected, outwith any evidence of negligence or recklessness, so as to gain the requisite information. Interestingly, the industry's sustained efforts to improve safety have also led to financial (and ecological) benefits through efficiency savings (Lucas 1987).

2.7.2.3 Reporter behaviour outside healthcare

Reporting is of course, like other human behaviour, also vulnerable to the cognitive shortfalls that can manifest in errors. Lawton and Ward (2004, p236) have argued that 'the attribution of human error is no more than a post hoc rationalisation based on hindsight' which is probably a reasonable description of error reporting. However, reporter behaviour is also subject to a range of motivational influences. Clarke (1998) questionnaired 128 train drivers and found that incident type, not wanting to see others get into trouble, and the expected response from management (whether action was taken as a result of reporting) were key. Furthermore the interaction between the expected management response and a personal belief that incidents were 'just part of the day's work' (p14) was significant. Clarke (1998) hypothesised that reporting could be an indicator of workers' perceptions of management's commitment to safety, but also identified that – as the study was conducted in three distinct geographical areas, these perceptions appeared to differ by local group or indeed subculture. Through a quantitative, retrospective analysis of accident reports, Prosser (2003) identified a low level of near miss reporting in the British Fire Service, which was similarly thought to be

related to complacency – and these included near miss injuries to the fire officers themselves. Caution should however be exercised in directly comparing results from studies of self-injury reporting to error reporting as there may be perverse motivations to *avoid* reporting as described by Daniels & Marlow (2005), including loss of pay (Grunberg et al 1996), or attracting adverse publicity (especially in a macho culture) where any financial incentive is group based (Macfie 1997).

The format or design of the report may also have a bearing on reporter behaviour. If the form is either too complex and or time consuming, the reporter may snub the form as was previously found in the construction industry (Pimble & O'Toole 1982). It is also evident that without specific guidance, workers will be less able to report (Leigh et al 2004).

Lastly, reporting behaviours are unlikely to be static. It would seem socio-political changes have even had an impact on what is often perceived as one of the better models of reporting (DoH 2000a, p44). The British Airline Pilot's Association surveyed 534 pilots recently on the effects of fatigue and claimed that the demand for more and cheaper flights has led to pilots working much longer hours. Significantly, some of those surveyed said the subject was taboo owing to the threat of disciplinary action, and this was reflected in its absence as a contributory factor in incident reports (Symonds & Shoesmith 2007).

2.6.3 Incident reporting in healthcare: purpose and development

Twenty three years ago, the American Lucian Leape argued that many medical incident reporting systems lacked analysis and therefore an inability to surface root causes (Leape 1994). Six years later, Leape (2002) re-appraised the role of incident reporting, reiterating its importance in exposing faulty systems and attempting to defuse some of the concerns around reporting in general. There is now little doubt that incident or adverse event reporting is judged to be of substantial value to patient safety. The World Health Organisation having

proclaimed its support through draft guidelines for reporting systems (WHO 2005). The WHO Guidelines drew on a literature review, an international survey of systems, and expert opinion, concluding that reporting should be centred on learning, and not punishment, but that the response to the report rather than the report itself is the agent that can improve systems and as a consequence, safety. It has been argued that some of the trepidation around reporting relates to its purpose being misunderstood (Pronovost et al 2004).

The central purpose of incident reporting is monitoring, so that problems (or incidents) can be identified before they lead to greater problems or incidents (Beckmann et al 1998). Two discrete objectives have been described by Runciman et al (2001, p298); first, reporting should identify any professional whose competence is well below standard, together with any substandard processes or conditions, and consequently address such deficiencies *locally*. Secondly, information must be collected that will show where and why errors have occurred in terms of existing systems rather than identifying the individuals involved. Runciman et al (2001) substantiate *their* distinction by claiming that some practitioners are clearly reluctant to report and any reporting process which calls for identification of substandard individuals, is at odds with the acknowledgement that the most errors stem from 'faults in the system rather than faults in the individual' (Runciman et al p298). Runciman et al (2001) also advance the ethico-legal elements of reporting suggesting that selected information concerning substandard practice and conditions is properly validated and then made public, but again in tandem with the human error theory, they accept that substandard practices only account for a small number of medical errors.

Incident reporting is a relatively new term in NHS parlance. Its geneology is rooted in the notion of accident reporting where typically a nurse representative of the clinical team would complete a short, often one-sided form which would demand details of who, where, what and how an accident took place. The accident form

would inevitably be sent to a more senior nurse who would then make a decision as to whether a more senior manager should be notified. The nature of the accidents reported were often concerned with working conditions rather than the patient and their clinical care, probably because the policy drivers behind accident reporting stemmed from the Health and Safety at Work Act (1974), and the need to collate records of employees' accidents to justify any claims for sickness or incapacity benefit.

Progress in healthcare reporting was often confined to specialist corners of the service such as anaesthesia, where it appears 'critical incidents' were first investigated using human factors by Cooper et al (1978). A major leap forward in the development of incident reporting, again influenced by the seminal work on critical incidents (Flanagan et al 1954), was accomplished by Runciman and colleagues (Webb et al 1993). With the co-ordinated support of the Australian Patient Safety Foundation (APSF) they set up the Australian Incident Monitoring Study (AIMS). The initial focus was again anaesthesia which was also the background of the researchers. Several reporting principles were established in what was initially a paper-based system: to include all incidents (which also meant adverse drug reactions and near misses), voluntariness and anonymity. There was also a definitive structure to the report form (1-10) and the process (11-15):

1. Instructions for the reporter
2. Free text narrative with key words (the key words progressively emerged from the collected data)
3. 'What happened' section
4. 'Why it happened' – termed 'contributing factors' (predominantly systems factors)
5. Factors minimising the incident
6. Suggested corrective strategies
7. Procedure being undertaken

8. When the incident occurred
9. Where the incident occurred
10. Outcome of the incident
11. A ‘person on the spot’ coordinated and supported the reporting process in each clinical location and provided a forum for discussion if appropriate
12. Vicarious reports were discouraged [i.e. where the person closest to the error was not the reporter]
13. The reports were then forwarded to the APSF with no identifiable origin
14. The APSF standardised key words to promote effective data retrieval and analysis
15. Summaries of the data analysis were periodically sent to the Royal Colleges

The first 2000 reports received were subjected to a rigorous analysis. Webb et al (1993) found that 75% of the reports were complete, missing data was detected by the absence of key words. Average narrative length was 96 words. It was also found that the nature of the incident was often unusual or actually/potentially dangerous, and it was hypothesised based on Flanagan’s earlier work that reporting is made as convenient and easy as possible to allow more mundane incidents to be reported, as the greater the challenge to report the less likely the mundane will be reported. The authors also argued that the more (systems) detail provided, the less likely a ‘witch hunt’ would take place (p524). A systems-centred language was chosen for the contributory factors list, [e.g. ‘error of judgement’, ‘inattention’], and the broad sweep taken included factors pertaining to active failures as well as error-producing conditions, and traditional systems factors. Webb et al (1993) also made it clear that they wanted to establish whether there was any correlation between the various variables identified such as phase of anaesthesia and level of harm. Webb et al’s early paper led to many other papers by the same team of authors specifically dedicated to the incident reporting process

and its potential as a risk management tool, which prompted Vincent (2006) to describe this bed of research and development work by Runciman and his colleagues as pioneering. The Australian group demonstrated a fundamental confidence about the benefits of reporting, especially its relative cost effectiveness, and ability to capture contributory factors (Malpass et al 1999a), or more broadly speaking - contextual information (Runciman & Merry 2003).

Effective reporting for Runciman et al (1993), acknowledges the theoretical concept of multiple causes at different levels and that human performance is context dependent, having a direct parallel with Reason's later paper on the ingredients of error wisdom (Reason 2004). Runciman et al (1993) also share Reason's position on blame, having argued that it is an inappropriate response that detracts from the central mission in error management – to find the contributory factors, and that this should be made explicit to reporters. Thus reporting, as described by Runciman et al (1993), must facilitate an understanding of the relative frequency of the most significant factors and their impact so as to ultimately move from retrospective analysis to causation and eventually prevention (p516). From a data base of 2000 reported incidents (not just adverse events), a hierarchy of causes was constructed using natural mapping. Reason's standpoint on the concatenation of individual and systems factors informed the approach with Norman's theory of natural mapping, the latter being where categories of incident type alongside primary, secondary, and subsidiary contributory factors are iteratively mapped by their natural, contextual connections (Norman 1988). They were also identified as either active or systems failures, typically: head injury from patient fall [event category], poor balance [contributory factor or natural link], history of Parkinson's disease [co-factor/link], lack of mobility assessment [subsidiary systems category]. Runciman (1998) termed this the Generic Occurrence Classification (GOC). There were logistical challenges. A computer-based system would allow users to click on their chosen category which would then expose a further range of choices, but the

process at the time of the pilot study was paper-based, also the number of categories made available would be dictated by the level of detail in the report. The GOC was tested using data from two large epidemiological studies (Wilson et al, 1995, Thomas et al 2000). The authors concluded that a more rigorous quantitative evaluation should be carried out but that the GOC was twice as fast as having reporters assign key words. Face validity was judged acceptable as the dominant categories were identified on 93% of occasions, and these represented 94% of all adverse events from the test data. The Australian group made a sustained effort to improve reporting. However, reporting attitudes for those with a history of five years access to the AIMS system, recently examined through an anonymous survey of 186 doctors and 587 nurses (overall response rate 72.8%), demonstrated considerable ignorance and reluctance concerning reporting (Evans et al 2006).

Elsewhere, there are a range of different approaches to reporting, the details of which are shown in table 2.2 overleaf (adapted from WHO, 2005)

Table 2.2 Different approaches to reporting by country

Country	**Type of reporting scheme**
Czech Republic	Mandatory but voluntary in 50 hospitals Reporting and analysis at local and national level, and by speciality No public access.
Denmark	Mandatory but separate from any punitive process Reporting local and national, analysis at local level No public access
Holland	Mandatory for serious adverse events, otherwise voluntary Analysis at local level Annual report to public only
Ireland	Voluntary, local paper-based system but web based national system Analysis national No public access
Japan	Voluntary but mandatory for teaching hospitals [rationale unavailable] Electronic reporting with national reporting system Analysis national with feedback Reports to public from National Council
Slovenia	Voluntary for sentinel events Analysis at national level Public access to anonymised reports via internet
Sweden	Described as regulatory as legal requirement to report Reports submitted by health professionals and public Paper-based system with regional analysis and link to disciplinary action
United Kingdom	Voluntary, web-based national system, national level analysis, public can report but not access health professionals' reports.
United States: [no national system]	21/50 state systems have mandatory reporting Some degree of public disclosure in all states Serious adverse events can trigger on site investigations *(i) Institute for Safe Medication Practice* Similar to UK MHRA. Voluntary system for adverse drug events and hazards in medication delivery. Reports received through range of methods including on line. Patients can also report and has link to disciplinary action Feedback via hazard alerts. Regulates packaging, devices, and equipment. *(ii) Joint Commission on Accreditation for Healthcare Organisations* Voluntary system for learning from sentinel events. Organised by accreditation body but credit status not affected by reporting as long as due process is followed. E reporting. Root cause analysis necessary at local level. Feedback via sentinel event alert. *(iii) United States Pharmacopoeia (Med Marx)* Voluntary system designed to identify hazards and system failures Reports received through range of methods including on line. National analysis through database. Annual summary report [unclear as to level of public involvement]

In the UK, the government's initiative on clinical governance is underwritten by a statutory duty to monitor the quality of care provided and '[implement] critical incident reporting [which] ensures that adverse events are identified, [and] openly investigated lessons are learned and promptly applied' (DoH 1999); however the act of submitting a report is voluntary. Additionally, the NHS Plan (DoH 2000b) asserted that the health service required a more systematic, time-efficient and patient-centred approach to investigating and addressing claims for clinical negligence and any resultant compensation. This was to be achieved through the Clinical Negligence Scheme for Trusts (CNST) and although entry to the scheme is not mandatory, a trust must have among its various risk management strategies, an incident reporting system so as to qualify. A survey in 1998 showed that out of 169 NHS trusts, just under 20% had still to implement a trust-wide reporting strategy (Dineeen and Walshe 1999).

'An Organisation with a Memory' (DoH 2000a) consolidated the value which is currently assigned to incident reporting by central government, arguing that for organisational learning to occur, there must be organisation-wide reporting. Incident reporting is now a central component of clinical risk management. It is evident in the NPSA's Seven Steps to Patient Safety overview and, in line with the Department of Health, it emphasises the importance of learning through reporting near misses as well as adverse events (NPSA, 2004). An 'Organisation with a Memory' also advocated the introduction of a national reporting system which would be based on standard local systems and confidential. The NPSA carried out a small pilot survey of 18 NHS trusts (12 being acute trusts), over 10 months, to test the feasibility of the system (Shaw et al 2005). The authors admitted that the non-random sample, although geographically widespread consisted of organisations who were particularly interested in risk management. The focus was on outcomes rather than process, which was helpful considering the broad range of reporting processes and technical specifications. Outcome measures included:

error type, adverse event or near miss, risk rating, and specific demographic details such as patient gender, age, speciality and location. A total of 28, 998 incidents were reported, of which 95% were from acute trusts. Slips, trips and falls, and medication incidents were the most common incident types. While 138 and 260 incidents were classified as catastrophic and major respectively, there seemed to be inconsistencies in the taxonomy of the 2514 medication management incidents. Something called 'medication errors' was classified separately from administration errors (p282). The authors also claimed that the results yielded a 'gratifyingly rich data set' and that staff were 'sufficiently concerned to…make reports' (p282); however, this is rather at odds with some of the more recent conclusions of the NPSA observatory discussed below (NPSA 2005a), and that of the empirical studies discussed in section 2.7 on barriers to effective reporting.

The mass migration to incident reporting is demonstrated in the NPSA's first report on their National Reporting and Learning System (NRLS). This has stated that all NHS organisations in England and Wales are now linked to the NRLS, a process that demands the same organisations have an established organisational reporting system (NPSA 2005a). The NRLS thus presents an opportunity to analyse a *national* data set of incident reports. From the key data, it is has been extrapolated that there are five incidents reported per 100 admissions to acute hospitals, and that patient factors (38%), insufficient communication (14%), and task factors were prominent contributory factors. Communication and knowledge problems were common across different types of incident. Interestingly, the categories of contributory factors demarcated by the NPSA show considerable conceptual overlap (see Figure 2.5). However, although the volume of reports received by the NPSA has steadily increased since the creation of the NRLS, over 10% of incidents had no contributory factors recorded and for most incidents just one factor was recorded (NPSA 2005a, p55). Furthermore, a recent NPSA analysis of the quality of reporter's free text showed that 10% of reports on patient falls have less than 30

characters and lack comment on perceived causes, in spite of falls being a major issue in risk management (Scobie, 2007). These observations may also point to difficulties of data collection and analysis at local level. Since the AIMS analysis of 2000 incident reports demonstrated the need for continuous pulse oximetry during anaesthesia, Runciman (1998) has consistently argued that free text has an inherent value. However, to really discriminate what has occurred in an incident, the reporter must deliver a logical and sufficiently detailed reflection and the reader must have the expertise to perform an adequate analysis (Billings 1998a, Vincent 2006, Armitage & Chapman 2007).

Figure 2.5: NRLS Categories of contributory factors
(Source: NPSA 2005, First Report of NRLS and Patient Safety Observatory p55)

- Patient factors
- Communication factors
- Task factors
- Work and environmental factors
- Equipment and resource factors
- Organisational and resource factors
- Medication factors
- Education and training factors
- Team and social factors

Risk managers are those generally employed by NHS trusts to manage those mechanisms that process incident reports (referred to as readers) and commonly appear to play a leading role in selecting incidents for detailed analysis. Based on the author's observations it appears many have not enjoyed the opportunity of specific training other than root cause analysis. It is difficult to ascertain the influence exerted by those responsible for the operational management of reporting in a healthcare organisation but what they are [e.g. equivalent to a service manager], and what they were – a nurse or safety expert, may dictate how they are perceived. It has been suggested that where a single risk manager covers an entire trust, rather than a range of 'local' risk managers each existing in their separate units, reporting rates may be comparatively lower (Stanhope et al 1999). The NRLS, has indicated there is a wide variation in the volume of incidents

reported across the NHS, but for those trusts who have the greater reporting rates there will be a greater burden of routine analysis; a process which is, in paper-based systems, often reliant on untrained data entry clerks (Armitage & Chapman, 2007). In fact a large volume of report data can be a problem in itself – an increase in quantity is not synonymous with a relative increase in quality (Wachter 2004).

2.7.3.1 Electronic (e) reporting in health care

The continuing advancement of information technology, particularly in healthcare, has also led to an increase in electronic rather than paper reporting both at local and national levels. This would seem entirely appropriate as practitioners have asserted that devoting long periods of time to filing a report is a barrier to submission (Uribe et al 2002, Evans et al 2006) as described below, and notably low reporting rates have emanated from studies of paper-based systems (Cullen et al 1995, Stanhope et al 1999). In a single New York hospital where the State operates a mandatory reporting system, Tuttle et al (2004), introduced a voluntary e reporting scheme, and then measured the impact on reporting and the accuracy of the reported data over a one year period. Training was given to reporters who could then access a comprehensive drop down menu function to attribute event types, impact and contributory factors, and a free text space for incident description. Options were given for contributory factors which included: system, equipment, human, environmental, and patient factors. The authors found that the per annum reporting rate had almost doubled in comparison to the previous paper-based system, with nurses reporting the bulk of events (73%), and doctors just 2%. Interestingly, near misses contributed to 10% of all submitted events. This study although specific to the development of electronic reporting also surfaced data and prompting processes that are pertinent to reporting schemes in general, especially that active failures were judged by reporters to figure in 50% of events, system factors less than 10%. An associated 'culture survey' using a Likert scale, was

also administered but only achieved a 10% response rate. While cultural issues in reporting will be discussed in detail in the concluding part of this review, the level of response to the survey may have been suggestive of a general lack of interest in reporting - in spite of a full training programme being implemented (and a relative rise in the reporting rate). Furthermore, 85% of respondents believed the new process to be cumbersome which may consolidate this view. The specific advantages of e reporting were seen to be the creation of a data warehouse and consequently the option of providing more effective feedback. Other advantages cited were the provision of a nomenclature to define and quantify harm but this would be equally achievable through a paper-based system, however miscoding of incidents was not uncommon despite pre-coding.

In a Japanese quality improvement initiative, Nakajima et al (2005) introduced a web-based reporting system for hospital physicians, which they described as a 'systems orientated approach' (p123). Among their various lessons learnt, they suggested that a web-based reporting system can help promote a safety culture. The university hospital which conducted the initiative had responded to national health policy by collecting data on actual and potential patient harm but recognised that only the Nursing Department had gathered such data, it was not shared out with the department, and it was perceived as a 'written apology' (p123). Based on the notion that physicians prefer electronic reporting to paper-based systems (having referred to just one empirical paper cited to support the claim – O'Neill, 1993), the decision was made to move to an electronic system, but also one that was anonymous. The authors, in common with Tuttle et al (2004) also used structured options, but in the form of sequential prompts. Thus if the reporter selected as an incident type 'medication', they would then be asked to click on drug type, and then stage in the process, [e.g. dispensing]. Nakjima et al (2005) identified a number of advantages to electronic reporting some of which could also be seen as first principles of effective reporting: easy access to the system, swift

completion, and structured data entry. Although reporting was the central topic in this paper, reporting was just one part of a range of integrated projects to advance risk management. For example, middle managers *across* the disciplines were appointed as area risk managers and as well as facilitating reporting, they also were seen as the hub of risk-related communication with staff and patients alike. Reporting rates increased as in Tuttle et al's study, almost half of reports were medication related, and the leading causes were protocol violations, poor communication, and inadequate supervision. Again, in common with Tuttle et al, there were cultural observations such as doctors preferring to engage in incident analysis within their professional group even if the problems (and associated learning) were transferable to other domains, [e.g. poor team communication]. Similarly a data warehouse was also created which again allowed for the easy dissemination of newsletters, but notably the authors found no evidence to demonstrate that this type of information passage had any more than a very limited effect on future incident prevention. Finally on a practical note, the author (GA) has observed that access to computers in the NHS is sometimes limited, and that there are still gaps in computer literacy among NHS practitioners.

2.7.3.2 Anonymous reporting in health care

This approach to reporting is contentious. Assumptions are sometimes made about the prevalence of anonymous systems, this is well exampled by Rosenthal (2001) who listed the characteristics of 'adequate' reporting systems which included reporter anonymity and ease of access, and claimed that patients and public are likely to accept anonymity in the pursuit of error reduction. Vincent (2006, p65) has taken a different stance, drawing on Runciman's premise that their must be a balance between accountability and learning, asserting that the requirement of accountability is based upon a 'core professional responsibility' to report, and thus anonymity is not required. Vincent also added that the audit trail necessary in any subsequent investigation would also be limited as the protagonist might be

untraceable, which is also identified as a difficulty by Suresh et al (2004) in their trial of voluntary, anonymous, reporting of medical errors in 54 neonatal units. This is arguable. Both risk managers at King's College Hospital, London (personal communication 22.3.06) and Alderhey Hospital, Liverpool (personal communication 2.5.06) have stated they can trace the protagonist without having their name on the report, there being sufficient other recorded details provided, [e.g. patient ID and clinical location/time]. In fact, both risk managers added that the protagonist, as a consequence of their professional responsibility, will also report to their immediate superior as part of submitting a report – thereby providing another option for tracing. It has been found from a survey of 2,500 medical staff by Doctors.net.uk that they simply do not trust reporting systems that are non-anonymous as they continue to sense a blame culture (BBC News Online, accessed 2.12.04). A particularly low number of reports, compared to other professionals, was received from doctors by the NPSA's NRLS in its first year – even though anonymous (www.npsa.nhs.uk.staffreports), which suggests the well published barriers such as fear of managerial action (Lawton & Parker 2002, Uribe et al 2002, Kingston et al 2004, Evans et al 2006) can be persistent. There is however a paradox here, Berman & Collier (1996) hold that anonymous systems, by valuing confidentiality are at odds with the development of an open reporting culture, as they imply the need for protection from management. The debate on anonymous reporting is also an insight into the culture of reporting.

2.7.3.3 Reporting drug errors

The increasing prominence of incident reporting was also reflected in the Department of Health's first specific policy document on medication safety which explicitly stated:

'Local [reporting] schemes should be encouraged but must ensure reporting of errors through the National Reporting & Learning System' (DoH 2004, p145).

The policy drive in the UK, is broadly comparable to that in North America, Australia and some European countries such as Denmark, but has not led to the mass development of tailor made drug error (and or medication incident) reporting schemes at a local level even though, as discussed earlier, medication incidents remain one of the leading types of reported incidents, especially in acute care settings. That Barber et al (2003) have contended that the act of prescribing is not essentially seen as critical – witness the detail sometimes imparted from consultants to junior doctors about commencing a drug – could suggest drug errors are somewhat marginalised despite the policy hype. As the subsequent systematic review will identify, appraise and synthesise peer reviewed empirical knowledge of drug error reporting schemes, it is outside the scope of this background review to add any further detail.

2.8 Barriers to effective reporting and the culture of reporting in healthcare

There are many barriers to the effective reporting of health care incidents and errors. Cognitive, socio-cultural and technical factors can create these barriers. The former will be discussed before considering socio-cultural factors which form a much greater proportion of the dedicated empirical and grey literature on barriers. Technical factors have been largely covered in the previous sections concerning electronic reporting which concern access, retrieval and feedback of report data. Suffice to say that poor access to a reporting process can be a significant deterrent to reporting. While the barriers here are organised into these three convenient groups, they should not be seen as mutually exclusive.

Cognitive factors include [the reporter's] recall of information (Reason 1990), and a range of cognitive biases or mental shortcuts to ease decision-making including hindsight bias (Fischoff 1975), the availability heuristic (Tversky & Kahneman 1973), fundamental attribution theory (Jones and Harris 1967), outcome bias

(Baron & Hershey 1988), and confirmation bias (Nickerson, 1998). These cognitive factors, as has already been discussed, are also causes of error.

As reporting is by nature a retrospective act, hindsight bias is a constant threat to the effective reporting and analysis of errors. It was originally described by Fischoff (1975) in a series of experimental studies where subjects were invited to predict the likelihood of [known] notable historical events occurring before they occurred and recall their predictions. They remembered their predictions as a reflection of what had actually occurred and declared little surprise at the eventual events. In an associated experiment, subjects read briefs of more obscure historical events, judged the likelihood of various outcomes and were then told what had actually happened. Their subsequent judgements with the benefit of hindsight showed that they assigned a higher likelihood to outcomes once they knew they had occurred, they also felt that any information supporting this outcome was more relevant than any other. Applying these findings to reporting, humans are more likely to remember consequences rather than 'causes', but base any assumption of cause on preferred alternatives – often just one – self-confidently informed by gut instinct rather than a systematic appraisal. Additionally, as Fischoff concluded 'the very outcome knowledge which gives us the feeling that we understand what the past was all about may prevent us from learning anything about it' (p299). The closely related availability heuristic is where individuals base their prediction of an event outcome on its emotional impact rather than its probability – this heuristic could again act as a mental obstacle in identifying the causes of a given event. Fundamental attribution theory is somewhat different. It is self-referential in that it proposes individuals are more likely to attach a poor behaviour (or outcome) to someone they consider less than effective – the cause being their personal disposition, yet if one personally experiences a poor outcome it is thought to be more likely to be owing to external (uncontrollable) forces. Like the other biases, this could potentially affect the judgement of a manager around causation when a

reporter who has previously been seen to be at personal fault in a drug error, then makes another and an investigation is required. Outcome and confirmation bias are similar but different. Outcome bias is the tendency to judge an event by its outcome at the expense of any process considerations; whereas confirmation bias is where an individual might favour causative factors that reflect their currently held view on an outcome (Reason 1990, 168-9). The latter two biases are again potential value-laden obstacles to the analysis of the contributory factors in a drug error and the nature of its outcome.

Other barriers to effective reporting will be influenced by individuals' personal beliefs around the perception of risk, but also from their host organisation's attitudes towards reporting, as well as the response of their peers. Professional and other cultures will have a bearing on these influences. Indeed it has been suggested that hospitals are rarely single cultures but more likely a fragmented collection of subcultures divided by professional, speciality, departmental, and even duty roster boundaries (Carroll & Quijada, 2004). While dominant cultures take time to mature and create the collective change in behaviour that is desired, ultimately the beliefs therein could affect the nature (and quality) of data provided when a report is actually submitted, or even, prevent reports being submitted at all. Professional autonomy - a prevalent value among many professional groups – especially doctors, and inter-professional hierarchies, are phenomena that can prevent the necessary co-operation that is required to deal with multi-disciplinary problems such as drug errors and multi-disciplinary initiatives such as drug error reporting. As Berwick and Nolan (1998) have pointed out, the most germane skill necessary to instigate improvements in safety (and quality) may be the ability to co-operate across professional boundaries – something that may be equally germane to the more specific challenges of incident reporting. Indeed it has been stated that lessons from report-based investigations are rarely shared (WHO, 2005).

In a large Australian, anonymous questionnaire-based survey mentioned above,

Evans et al (2006) demonstrated that there are clear inter-professional and intra-professional differences in reporting and likely, differing views concerning its inherent value. From a sample of 186 doctors and 587 nurses (response rate of 70% and 73% respectively), Evans et al (2006) presented a number of statistically significant findings. First, that doctors were less likely to report than nurses, especially senior doctors, indeed 40% of seniors had never completed a report – the system for which had been largely devised by William Runciman and his anaesthetist colleagues. Although senior nurses were more likely to report than their junior counterparts, those with more than five years experience were more likely to believe that the process of reporting near misses was pointless. More insidious incidents such as pressure sore development, were less likely to be reported. Just 42% of staff felt that drug near misses should always be reported, and acts of omission were seen as less worthy of reporting than commission. Using data drawn from a 5-point Likert scale, lack of feedback was the overarching disincentive for two thirds of respondents, allied to a disappointment with lengthy forms and a perceived lack of time to report. Interestingly Evans et al (2006, p42) conclude that the barriers to doctors' reporting are organisational rather than cultural and that the views expressed crystallise the belief that 'only bad doctors make mistakes'. Data were also collected at a similar time from 256 NHS trusts as part of a survey of patient safety-orientated learning and reporting by the National Audit Office (2005) who quantified and ranked the five 'top reasons' for under-reporting:

1. Fear (19%)
2. Poorly designed forms (15%)
3. Lack of understanding about what to report (13%)
4. Failure to recognise an incident (11%)
5. Being too busy (10%)
6. Lack of feedback following submission (10%)

The National Audit Office's (NAO) hard copy does not provide extensive detail about their methodology, however, it was noted that as well as employing a questionnaire, the NAO also visited an undisclosed number of trusts to interview staff from senior management to the shop floor. Only one trust failed to respond to the questionnaire which was based on the criteria originally developed by DoH (2000a) for appropriate cultural and systems markers for learning and reporting. The data were collected against a back drop of an increasing reporting rate, with 38% of trusts having an anonymous option, including some for drug errors. Notably, staff believed that under-reporting was a particular issue with drug errors where there was more concerns about personal consequences. It was also held that an increase in near miss reporting indicates a healthier, fairer reporting system - largely based on the work carried out by Heinrich (1980) that for every serious adverse event, there are 29 minor accidents, and 300 near misses. The survey found a variable rate of near miss reporting hampered by definitional problems, with acute trusts showing five incidents to one near miss.

A series of other, less recent studies demonstrate comparable findings. Some years earlier Vincent et al (1998), again using anonymous questionnaires administered to 42 obstetricians and 156 midwives (98.1% midwife response, 84% medical response), but only in two English obstetric units, established similar professional differences. Firstly, 90% of staff knew how to report but 20% less knew what to report, secondly the authors were able to rank the reasons for not reporting: a needless task, a detrimental impact on workload, possible blame, and that it hampered the pace of work. Importantly, the authors clarify that any concern about staff judging reporting to be unnecessary should consider that studies of 'incident' reporting also include non-preventable incidents, [i.e. those not involving error]. However, the stated attitude may still be suggestive of the value given to the patient safety drive, in this study prior to the major policy document 'An Organisation with a Memory'. Lawton and Parker (2002) conducted a multi-

centred study in 1998 in 3 NHS trusts – again using a questionnaire (53% response rate) to determine attitudes to reporting - but with case scenarios that respondents were to imagine they had witnessed. This study established that incidents with bad outcomes were more likely to lead to reporting than those with poor outcomes, and those with good outcomes were even less likely to be reported showing commonality with respondents from other studies where practitioners were reluctant to report near misses. Lawton and Parker (2002) questionnaired doctors, midwives and nurses and again found a greater unwillingness among medical staff to report. Lawton and Parker also explored the social psychology of rule (protocol) violations in the scenarios and found that midwives and nurses were also more likely than doctors to report such a violation, regardless of outcome. The authors concluded, in line with Rosenthal (1999) that this could reflect a 'profession in which whistle blowing is taboo'; they also however added that this was not a randomised study, and that self-reporting questionnaires – in spite of anonymity can be contaminated by social desirability effect. Of particular note was the author's suggestion that the future design of reporting systems should prioritise learning and might benefit from the principles of human error theory.

Recognising the chronic problem of under-reporting evidenced elsewhere (Barach and Small 2000), Uribe et al (2002) mounted an exploratory survey of barriers to generic incident reporting among doctors and nurses in a North American medical centre. Following a nominal group technique to generate questionnaire items through a multi-disciplinary sample of 9 professionals, a total of 705 questionnaires were distributed to two random, quota samples but only achieved a 17.3% response rate. The most likely barriers identified were: time involved in submitting a report, the allied extra work, 'telling' on someone else, and the belief that a near miss report is unnecessary owing to its outcome. Additionally, physicians perceived more barriers than their nursing counterparts, but the nurses were more concerned about anonymity, suggesting that blame was more of a concern for them

as a group. Important limitations included that the results were a reflection of what the respondents believed prevented them from deciding to submit a report rather than the organisational reality – in other words – a range of *perceived* barriers. The authors recognised the importance of multi-disciplinarity in their conclusions, which incorporated the need for unified understanding through clear error definitions, guidelines and concerted, constructive feedback. In another North American multi-disciplinary study, but based in a children's hospital, Taylor et al (2004) also used a survey questionnaire to both describe the proportion and types of medical error reported as well as attitudes to reporting and which interventions might improve the process. A total of 140 questionnaires were returned (70% response rate) and analysed using χ^2 to compare variable proportions, and logistic regression to assess the independent association between professions and their likelihood to report. The authors gave practitioners scenarios - designed by a multi-disciplinary panel, and assessed practitioner's propensity to report through a Likert scale. Respondents were asked when, if, and how many times they had reported in the past year based on their own (and others') incidents. Nurses were again found to report significantly more than doctors (OR 2.8, 95% CI 1.3-6). Apparently, there was considerable under-reporting, apparently because of uncertainty about implicating colleagues as well as what to report. It was felt that feedback (63%), response through evidence of systems changes (55.4%), and electronic reporting would be valuable interventions. There was also an inclination to report adverse events rather than near misses, illustrated in the extreme by asking whether respondents would/would not report a near miss related to attaching a breast milk supply to an intravenous line. The authors concluded cultural change was essential to adequately address medical error reporting.

Kingston et al (2004) carried out a study in Australia with similar objectives but used a qualitative approach. A purposive sample of 14 medical and 19 nursing staff from three acute hospitals and four specialities were interviewed using a semi

structured approach in five focus groups. Transcripts were subjected to an iterative process of categorisation (using a theory of social behaviour - Triandis 1977), and independently co-rated with third party adjudication when necessary. The categories were subdivided by habit and intention, motivation and facilitating conditions. It was suggested that doctors were not habitual reporters, indeed it was maintained that 'nurses are the ones who initiate it' - one consultant believing it was nurses' relative powerlessness that made reporting their default position. Nurses apparently accepted reporting as an organisational imperative, but nevertheless questioned the quality of their reporting. It was also apparent that medical staff found reporting too close to the notion of whistle-blowing with all the inherent risks of losing peer respect, and although nurses shared a comparable sense of trepidation about the act itself, their duty to commit to [organisational] reporting was a more dominant ethic than the protection of immediate colleagues. This created some inter-professional tension – nurses being frustrated by doctor's general disinclination to report. Underpinning the nurse's commitment was the need 'to cover yourself' which, it was suggested, probably revealed their mistrust of the organisation in spite of their commitment to process. However, there was also a collective acknowledgement that reporting could be an opportunity to provide valuable information, *especially* if the reporting process was easy to use, blame free and egalitarian in response, providing feedback and possibly systems change. Although this study adds some depth to understanding the culture of reporting, the authors admitted that it harboured inevitable biases: the voluntariness of participants; and that [typically] in focus groups, individuals may conform to the majority view. This in turn limited – with other sampling factors – the generalisability of the findings.

Using an alternative qualitative approach but again with semi-structured interviews, Waring (2004) interviewed risk managers (16) and senior specialist medical staff (25) to establish an understanding of in-hospital variations in reporting and

underpinning attitudes within one hospital. The data presented from risk managers were limited compared to that from the medical staff, whom he selected on the basis of their involvement in risk management, but also using quotas to represent all clinical specialities. There was considerable mistrust of reporting from all departments except obstetrics. The latter, sensitive to the threat of litigation, but also influenced by national education initiatives, were generally positive. The rest especially the general surgeons were antagonistic to the process, in some cases ignorant of procedure, and concerned that it was out with medicine, run by management - and as a result - out of their control. Their preference was for locally driven processes, reflecting *their* management of such forums as mortality and morbidity committees. There was also strong support of anonymity for reporters.

In a second paper, also based on individual, semi-structured interviews, Waring (2005) specifically explored the attitudes of physicians to reporting, asserting that the research site - a single district hospital in England - was theoretically representative of many other acute hospital settings. Waring (2005) interviewed 28 senior doctors, encouraging practice-based narratives (2005, p1929), to facilitate an insight into their inherent attitudes and beliefs about the process. Like Kingston et al (2004), Waring exhibited some concern about the credibility of participants' responses mindful that they may have been 'portraying an image of competence' (p.1929). However, the author added that contextualising the data in relation to the array of quantitative studies (such as those above) could provide an assessment of the reliability of the data. Emerging categories were developed through the use of a constant comparative method (Strauss & Corbin 1990) which resulted in four conceptual themes. The first was centred on the fear of blame and reporting – fear apparently emanating from both internal (damaged career prospects or reputation) and external (litigation) sources. Indeed the majority depicted a process that was essentially about blame although some – more cognisant of the patient safety agenda, felt reporting had a practical raison d'être - illuminating upstream factors in

medical error. Secondly, it was thought that errors were inevitable, which perhaps invoked an acceptance of error which in turn served to demote the value of reporting. This belief is perhaps reinforced by the absence of feedback as Waring illustrated:

'what am I going to get out of it, or the patient…or my colleagues…and if they don't see anything valuable or a valuable lesson then people don't do it' (Respondent, Waring 2005).

Such concerns suggest that the grand aim of the World Alliance for Patient Safety to improve quality and safety through reporting and learning, which in their view hinges on the action taken following a report (WHO 2006), is not necessarily being achieved. A resolute conviction that reporting was a management exercise and had little to do with quality improvement further negated the need for reporting. This being in line with the view that practising doctors do not necessarily see medical error as a public health problem despite their awareness of the consequences, as demonstrated in Blendon et al's national, incentivised survey of 831 physicians (62% response rate) three years earlier (Blendon et al 2002). Thirdly, and linked to a rejection of managerialism and its attendant procedures, was a sense of paranoia that management was out to monitor them. This was further borne out by a confidential survey of over 3000 doctors conducted by doctors.net.uk: 78% of doctors said they had made an error but only 17% would submit a related report – 97% of doctors added that they would prefer an independent reporting system with electronic access and anonymous feedback. Lastly, Waring identified a strong sense among his respondents that reporting was about filling in forms, was definitively a nursing task, and outwith the discrete form of expertise that characterised medicine.

Barriers such as the notion of peer respect in medicine unearthed by Kingston et al (2004), chimes with Waring's findings concerning a culture of intra-professional

collegiality. Perhaps these qualitative findings reflect the relatively low reporting rates found among doctors compared to nurses and midwives as seen in the data from the first year of the NRLS (Vere-Jones, 2005), and elsewhere (O'Neill 1993, Stanhope et al 1999, Kivlahan et al 2002, Nakjima et al 2005, Evans et al 2007) sometimes despite the introduction of electronic reporting. Furthermore, a survey of 1318 medical staff in Norway which included an examination of attitudes to adverse events and acceptance of criticism found that 1:3 doctors had been responsible for at least one serious patient injury but only half the doctors questionnaired felt able to criticise their colleagues – which would presumably include the act of reporting another doctor's error (Aasland & Forde, 2005). It is possible that medical staff might eschew reporting *per se*, even if the practitioner is the one who has been harmed; Daniels & Marlow (2005) having documented that while surgeons suffer the most needle stick injuries they were least likely among health professionals to report them.

2.8.1 Voluntary versus mandatory reporting

The debate about voluntary versus mandatory reporting in healthcare – although not especially apparent in the UK is helpful in that it further illuminates the practice and also, to some extent, the culture of reporting. Cohen (2000), President of the Institute of Safe Medication Practices in the USA, has justified his stance on voluntary reporting by explaining that reporters will only tell 'the complete story without fear of retribution' (p728) and by forcing individuals to report errors (the mandatory model) they are less likely to provide the detail necessary to fully understand any contributory factors or indeed causation. For Cohen, professionals do not require force to report but, as would be available in a voluntary approach - freedom from punishment. In practice, Cohen claims that mandatory approaches 'imply' that the 'individual at fault must report the error' (p729) but that analysis of errors inevitably surfaces system failures and often the involvement of other individuals.

Perhaps unsurprisingly, it appears that mandatory systems are less popular than voluntary systems - indeed just 20 (of 50) states had such systems 5 years ago (Leape 2002). American States that operate a mandatory approach rate their success on the basis of numbers of reports received and Leape, citing a study by Rosenthal et al (2001), claims rates are particularly low – just six states receiving more that 100 reports per year. Leape (2002) also quotes reporting rates from the New York State Department of Health's mandatory Patient Occurrence and Tracking System in 1999, which he implied were low, however a more recent inspection of data from 2000-2001 showed a significant 61.9% increase in reporting rates (New York State Department of Health Annual Report, 2002). Research evidence on the effectiveness of mandatory and voluntary approaches is largely anecdotal, but Leape (2002) cites the twenty year old voluntary National Nosocomial Infection Survey which, having been tested by a controlled trial has apparently lowered hospital induced infection rates by 32% (Haley et al 1985). As a post script to the above debate on voluntary versus mandatory reporting, Cohen has argued that the voluntary or mandatory debate is futile unless analysis and feedback is effective – a view that does have some empirical support; Rozich et al (2001) having witnessed a considerable rise in reporting rates following the instigation of a rapid response approach. This chapter now offers a critical appraisal of medical error research.

2.9 Methodological issues in medical error research

Inaccuracies in measurement destabilise evidence of association or causation [e.g. in drug errors], and also threaten the valid assessment of impact in a given intervention such as a new incident reporting scheme. The principle problems with measurement generally concern: the choice of an accurate numerator or denominator, sensitivity of method (to detect errors/adverse events), and inter-rater reliability in for example, judging error types. The use of adequate operational definitions is a also a fundamental factor in achieving valid and reliable

measurement (Allen & Barker 1990) but as this has been discussed in detail in Chapter 2, it will not be laboured any further here.

2.9.1 Choosing an accurate denominator

It has been argued that one of the strengths of medical record or case note review is that a denominator is readily available (Olsen et al 2007) but it is accepted that even case note review is not without bias as the research setting with the more comprehensive medical records will provide the researcher with more data and hence more errors (Brown et al 2006). Brown et al (2006) have also proposed that the *opportunity for error* is preferable to a *per patient* denominator as it should alleviate problems related to case mix. Additionally, although many practitioners will be relatively equal in terms of competence, some may - due to the nature of their work - find errors more difficult to avoid. The denominator issue is especially problematic in the analysis of reported errors to establish a *reported* error rate. If the numerator is *reported errors*, the denominator should be all errors made. This would necessitate the simultaneous use of at least another method (ideally observation) - accepted as the gold standard - to identify the remaining errors. While such a standard has been proposed (see below, section 3.2.2), the process would probably be tortuous.

Different denominators can produce very different percentage values. The researcher who is trying to establish a reported error rate is more likely to have a higher percentage error rate if the denominator is admissions rather than doses given as doses given will simply be a much larger number than admissions.

2.9.2 Sensitivity of methods in error detection

Some errors will only be observable in their outcome and not their contributory factors [e.g. a lapse leading to an adverse event], and yet other errors will not have observable outcomes, [i.e. if they result in near misses]. The detection of error has employed several different methods, of which reporting is seen to be one of the

least effective. Differential outcomes (such as adverse event rates) according to each method, have produced a methodological hierarchy although the perceived sensitivity of each method is also considered against cost. Case note review was established as a method of detecting errors in the benchmark studies cited previously (Brennan et al 1991, Leape et al 1991, Wilson et al 1995, Thomas et al 2000, Vincent et al 2001). More recently, and with relevance to this study, it has been compared to incident reporting as a means of error detection. Four British (Stanhope et al 1999, Olsen et al 2007, Hogan et al 2007, Sari et al 2007) and three American studies (O'Neill et al 1993, Jha et al 1998, Rozich et al 2003) conducted in acute care settings have, in providing such comparisons, identified the problem of under-reporting. The results have shown that case note review consistently unearths more medical errors when compared to incident reporting. The exception is the study conducted by O'Neil at el (1993) from which incident reporting was found to have identified virtually the same number of events as case note review, 41 events were identified through both analyses, but 34 of the reported, definitive adverse events were not identified by the case note review. Furthermore, different methods produce their own unique collection of incidents (Hogan et al, 2007), as well as error types (Runciman et al 2003). Table 2.3 shows the results of these studies, which also identifies the incident type, which is inconsistent across studies, thus not allowing inter-study comparison.

However, case note review is not without criticism, it may harbour an under-reporting phenomenon (Naylor, 2002, and remains vulnerable to personal thresholds (Runciman et al 2003b.) Wald and Shojania (2003) also caution that identifying near misses is difficult (often due to the incompleteness of the record, Taylor et al 2004) and the process can be costly. In the context of this thesis, case note review is unlikely to elicit contributory factors (Beckman et al 1996), and case notes may be incomplete. The process of inter-rater reliability in such reviews has also received critical coverage, and consequently will be revisited

Table 2.3 Studies comparing case note review and incident report analysis in detecting patient safety events

Study authors and year of publication	Sources of data	Incident type and detection rate from case note review	Incident type and detection rate from incident reports	Denominator
O'Neill et al (1993)	Clinical incident reports from physicians only (email based), patient case notes	Adverse events: 85 (2.7%)	Adverse events: 89 (2.84%) *34 of which in reports only.	3128 admissions
Jha et al (1998)	Patient charts and clinical incident reports in patients admitted to 9 med/surgical units in an acute hospital	Adverse events: 13.3 per 1000 days or 398 (65%)	Adverse events: 0.7 per 1000 days or 23 (4%) [*over twice as many near misses identified from reports than other methods]	21,964 patient days
Stanhope et al (1999)	Clinical incident reports, patient case notes	Adverse incidents: 107 (54.6%)	Adverse incidents: 45 (23%)	196 adverse incidents from 250 consecutive deliveries in each of 2 maternity units
Rozich et al (2003)	Patient charts and clinical incident reports [Subset of main data set]	Adverse drug events: 274 (2.47%) [adjusted for % actually administered]	Adverse events 5 (1.8%) of 274 ADEs identified in case note review	1000 medication doses
Olsen et al 2007	Clinical and non-clinical incident reports, inpatient medication charts, patient case notes	Adverse events/clinical incidents: 26 adverse events 40 critical incidents (Total 22.9%)	Clinical incidents 4 (1.4%)	288 discharged patients

Study authors and year of publication	Sources of data	Incident type and detection rate from case note review	Incident type and detection rate from incident reports	Denominator
Hogan et al 2007	Incident reports, Health & Safety reports, complaints data base, claims data base, inquest data base, patient admin. system (PAS), random sample patient case notes	Patient safety incidents: 8781 (32.2%)* *projected estimate based on a review of 220 case notes	Patient Safety incidents: 484 (1.7%)	27, 270 in-patient admissions over 1 year
Sari et al 2007	Clinical incident reports, patient case notes	Patient safety incidents: 303 (93%)	Patient safety incidents: 54 (17%)	324 patient safety incidents (in 230 of 1,006 patient admissions over 5 months)

Observation is the other principle research method in medical error detection. One of the earliest observational studies conducted to examine the nature and causes of human error was based in an Israeli intensive care unit. Donchin et al (1995) collected data over a period of 4 months in 1989, using anonymised 'immediate' report data on specially designed forms; and 24 hour structured observation guided by an activity profile and carried out by observers familiar with human error theory. However, despite human error theory being mentioned in their paper, it was not referenced, indeed they appeared to construct a definition of human error for the sole purpose of the study. Donchin et al received 554 staff reports, and the activity profile showed a mean of 178 activities per patient per day with 1.7 errors per patient per day, including on average 2 'detrimental errors' per day. Error peaks were mapped on a 24 hour cycle, peaking in the mornings at the time of doctors' rounds – from which nurses were excluded. Nurse-doctor communication patterns were noted and verbal exchanges found to be particularly low. Although Donchin et al demonstrated that doctors and nurses appeared to contribute to a similar

number of errors, nurses carried out far more activities involving patients, per day. The authors acknowledged the effect of observer bias and that this was a specialist environment that was grossly understaffed. Andrews et al (1997) also used trained qualitative observers in a study of adverse events in a North American general hospital. They attended day shifts, handovers, notable departmental meetings, and case conferences to conclude that 185 out of 1047 (17.7%) patients had suffered at least one serious adverse event. Critically, the adverse event incidence proved to be much higher than in studies employing non-observational methods such as case note review. Observational methods have also been used to identify the causes of intravenous medication errors (Taxis & Barber 2003); the finer details of which will be discussed in section 3.5. Although this was described as an ethnographic study, a very structured observation process led to a calculation of the type, frequency and clinical importance of the errors. The observers accompanied nurses in their drug administration activities, but the nurses were not told of the true purpose of the study to reduce the impact of the researcher on their behaviour. Reducing the Hawthorne effect in this way however, threatens the autonomy of the observed participants, an ethical consideration which has been explored elsewhere (Armitage 2005). Nevertheless, Lilford et al (2003) have concluded that in spite of the expense, and potentially obtrusive nature of direct observation – it is the gold standard.

2.9.3 Inter-rater reliability

The benchmark studies of medical error (Brennan et al 1991, Leape et al 1991, Wilson et al 1995, Thomas et al 2000, Vincent et al 2001), by nature of their method, relied on the accuracy of case note reviewers reaching a valid and reliable agreement about two elements of adverse events: their severity and preventability. The most prevalent statistical method of assessing inter-rater reliability in these studies was the Kappa measure (Cohen, 1960), where the actual agreement between reviewers is compared with the agreement that might be expected by

chance alone. The application of this approach to the review of medical errors has however, been questioned (McDonald et al 2000), resulting in two empirical studies to actually test the reliability of the measure. First, Hayward and Hofer (2001) carried out a randomised, retrospective case note review of 111 patients who had died with specific hospital acquired problems. They aimed to assess the reliability of reviewers' ratings and the implications of a death described as preventable by better care, in relation to the probability of immediate/short term survival if care had been optimal. The 14 trained reviewers, blinded to the study aim were asked to rate preventability of death, and the likelihood of prevention if care had been optimal [i.e error-free]. Instead of asking the reviewers to resolve disagreements by discussion, it would seem that the authors simply examined the pattern of disagreement and demonstrated that reviewer assessment in studies of preventable deaths has poor reliability and is often skewed by phenomena previously mentioned such as outcome or hindsight bias. If reviewers evaluate records for preventable deaths, in most cases some reviewers will believe that death could have been avoided by different care, but the probability that error actually caused the death is often felt to be low, and that the underlying short term prognosis of the deceased is often judged as limited. Thomas et al (2002), as part of the Utah and Colorado study, measured the reliability and the effect of varying criteria for independent reviewer confidence in and agreement about, the presence of adverse events in 500 cases. The cases had already been selected for physician review which took place as normal but then the cases were put through two further, independent reviews using the same set protocol but blinded to the purpose of this (additional part of the) study. All reviewers completed a confidence scale. It was found that estimates of adverse events are sensitive to reviewer confidence and consensus. If a review protocol asks for a higher confidence score (and from all three reviewers rather than just one) in order to definitively classify an outcome as an adverse event, the total number of events will go down, but if the protocol lowers the confidence bar, the number of events goes up.

These studies have two connected implications: that the interpretation of adverse events will inevitably involve some subjectivity, and because of this - the details of how agreement is achieved must be made explicit by the researchers (Lilford et al 2003). Of course, even with poor to moderate reliability, the adverse events identified in these studies still provide an opportunity for learning and quality improvement (Thomas et al 2002), and any obsession with achieving precision should not overshadow the seriousness of an adverse outcome.

2.10 Epistemological and ethical considerations

Seale (2004) has argued that social researchers whose intent is to deliver quality work should not become tied to the problem of philosophical foundations, or the lack of them, as the research itself does not require these things to be 'resolved at the philosophical level'. He has however, advocated that researchers should also:

'be cognizant of the insights of both relativists and realists and pay attention to how [constructed] facts relate to [constructed] claims and theories'.

(Seale 2004, p411)

The complex structures and processes of healthcare organisations, and behaviours of their practitioners are instrumental in improving but also understanding patient safety. Consequently, this three year, three stage study draws on both quantitative and qualitative methods. Following the post-modern tradition, such methodological plurality should facilitate the exploration of different aspects of reality (Philip 1998) to capture the many complex, contextual phenomena behind error (Runciman 1993). The claims on the resulting data are made on the basis of the methodological perspective chosen. The analysis of archived and pilot incident reporting data employs quantitative and qualitative analyses. Data that provided evidence of the who, when, where and what variables in drug errors and reporting are interpreted at face value, from a realist perspective, in line with the recommendations of Gidley (2004). The free text in the incident reports are

interpreted as social facts (Atkinson & Coffey 1997:47), but not literal representations of reality, having taken a constructivist perspective. This perspective assumes that objective knowledge (or truth) is grounded in and developed from human interactions and social interactions (Schwandt 1997). It is then accepted here that particular practitioner identities are likely to be constructed through incident reports just as patient identities are constructed through their case notes (Prior 2004); and to further paraphrase Prior, that the trajectory of the reports from the sharp end of practice to senior management will demarcate the territory and expertise of those involved.

Similarly, the interview data is judged with caution in accordance with the belief that social interviews are as much a product of the interaction between the two parties involved (Fontana & Frey 2000) and a *function* of the participant's perspective and context (Silverman 1985), as well as what was actually said. These data nevertheless provide a contextual awareness of drug error, reporting and its attendant culture to inform the development of an enhanced reporting system. However, some elements of the interview schedule ask practitioners to provide specific detail on future reporting systems, and these answers were treated as resource data and accordingly, were also analysed from a realist perspective. The theoretical framework for the study, largely drawn from error theory, is now briefly considered.

2.10.1 Theoretical framework for the study

This study is built on the theoretical framework of human error theory which has been used to analyse the factors in medical error (Stanhope et al 1997, Vincent et al 2000), drug errors (Dean et al 2002, Taxis & Barber 2003a & 2003b, Beso et al 2005), but also incident reporting (Buckley et al 1997). It is proposed that the 'New Look' (Woods & Cook 2003) has further refined human error theory as an applied theory for healthcare, having explicitly emphasised the need to consider individual but predominantly system factors and their interactive, jointly sufficient character in

the context of a continuous learning process. Such learning in health care could be enabled by reporting systems, as envisaged by the National Patient Safety Agency (Waring 2004). However, Reason (1991) has also cautioned that the multi-faceted, interactive, and sometimes stochastic complexity of causation can render retrospective reporting somewhat inadequate. Nevertheless, Reason (1991) has also accepted that if there is a collective analysis of a large number of reports, [as is developing in the NRLS], mindful of the nature of error, and inclusive of near misses, the potential of reporting can be increased. It is then argued that the human error perspective could also provide a suitable cross disciplinary platform upon which to build a reporting system.

2.10.2 Reflexivity

Following the recommendations of Patton (1999) on the quality of qualitative research, and prior to detailing any empirical method and findings, it is judged appropriate to include a summary of relevant information about the author in order to establish 'investigator credibility' (Patton 1999, p1198). The author has worked previously as both health care practitioner and more latterly a university lecturer. Having practised as a nurse for 14 years, several drug errors were personally experienced and witnessed, none serious and not all reported. During the years working as a lecturer, several of the author's (nursing) students also experienced drug errors and were supported and supervised accordingly. While the author has a close affinity with nursing and nurses, the study has taken a multi-disciplinary approach. The collection and analysis of data has not focussed more intently on any given phenomena because of an association with nursing, all emphases are attributed according to their relevance to the research questions.

There were several connections with some of the staff interviewed, although there were no social connections; professional relationships had previously existed between the author and one of the doctors, two of the nurses, and two of the pharmacists. The recruitment of participants was not however influenced by the

author's prior connections, and the known participants approached the author rather than the author approaching them. Additionally, although the author was given a great deal of support by the trusts senior managers who had openly declared their support, they did not influence any part of the data collection or analysis. They did though, through various committees, suggest some additions and alterations to the pilot report form in line with the Trust's policies and procedures for risk management. These changes are referenced in Chapter 9 related to the method for stage three, under specific considerations. Finally, the Department of Health had no bearing on the conduct of the study, although they were the funding body.

2.10.3 Ethical considerations

Protection of both practitioner and patient identities in a study of this kind is imperative. Although less of a concern here, any patient identities were concealed through immediately anonymising all incident reports including named patients. The risks of qualitative research should not be underplayed (Murphy et al, 1998). The raison d'etre of qualitative approaches - to develop a deep understanding of complex phenomena and their context from the participants' standpoint – is the result of intimate engagement with the participants (Silverman 2000). Notably, it was decided in collaboration with the Local Research Ethics Committee that the interview participants' personal details, in the event of describing their own or others' errors, whatever the circumstances or outcome of their actions, would not be released to a third party. This in part, reflects the position taken elsewhere (Armitage 2005), where the author has argued that medical error research should promote learning and not blame. This study has adopted a rigorous process of informed consent and confidentiality to reduce the risks to all those who have participated. Furthermore, the author was primed to offer or find additional support to any participant who was affected as a result of their interview. The specific ethical considerations for each stage of this study are also discussed under

'Method' in chapters 4, 6, and 9.

2.11 Conclusion

A fuller understanding of human error has been developed through the synergy of several scientific disciplines, discrediting some of the lay assumptions about human fallibility. Drawing on studies of cognition, behaviour, organisational psychology, systems engineering, and more recently what has been termed the 'New Look' (Woods and Cook 2003), an explanatory framework of causation and a rationale for favouring learning over individual blame has emerged. A key protagonist in error theory is James Reason who has not only deconstructed the ontology of human error to facilitate a much stronger acknowledgement of its inevitability, but has also developed several preventative approaches, such as error wisdom. The risk of error is more profound in areas of complexity, such as healthcare, where drug therapy and its intrinsic danger is a critical domain. Addressing errors in healthcare – an environment with multiple pressures, uncertainty, and finite resources (Woods & Cook 2003) is however, a major challenge. Reason's perspective and also that of health professionals such as Lucian Leape - who has carried out several key studies of medical error - informed by human error theory, has been embraced by policy makers across the developed world. More recently, Dekker (2006) has argued that Reason's conceptualisation of error can inadvertently lead to an oversimplification of causation falsely separating individual, local and system factors. Acknowledging the interactive nature of causative factors has obvious implications for error management but also error reporting.

While an epidemiology of medical errors and indeed drug errors has been established, the development of initiatives and interventions to combat error is less obvious. Some important steps have been taken in developing taxonomies to disentangle the complexity of causation, and specific work has been carried out around drug errors, although it has attracted criticism owing to its lack of theoretical

underpinning. What is known of error has not, however, been fully utilised in the incident reporting process, despite proclamations of its importance. Indeed evidence from the aviation industry on the association between reporting and the reduction of serious adverse events, has led to organisations such as the NPSA and the World Health Organisation (World Alliance for Patient Safety, WHO 2006) extolling the virtues of reporting. The Australian Incident Monitoring Study (AIMS) set an empirical base for a massive incident reporting scheme and appears to be a fine example of how reporting can create safety improvements, yet even the impetus of AIMS has not seen Australian health professionals fully commit to the process (Evans et al 1996). The literature demonstrates that many schemes lack sophistication, while others may be too complex, and perhaps as a consequence, they do not enjoy the unconditional support of their users. Cognitive, technical, and socio-cultural factors - conspire to reduce the effectiveness of reporting as well as the much maligned organisational response – seen as integral to systems improvement. Nevertheless, incident reporting has two important advantages: false positives are rare, and the clinical significance of errors is likely to be high (Flynn et al 2002). Furthermore, the advent of electronic reporting could ease the burden of both submission and analysis. Reporting is probably a curate's egg (Armitage & Chapman 2007). Unfortunately, a culture of blame may still be a part of individual and organisational psyches even though it is seven years since Kennedy's plea that:

'Every effort should be made to create in the NHS an open and non-punitive environment in which it is safe to report and admit sentinel events' (Kennedy, Final Report from the Bristol Royal Infirmary Inquiry 2001, p107).

Kaplan & Barach (2002) have argued that the most unique attribute of reporting is engaging health professionals *en masse* in safety activities - a stark reminder that organisations should not lose an opportunity from a readily available resource – this would however demand that reporting errors should be seen as a source of

learning rather than blame.

Finally, it is clear that both qualitative and quantitative methods can make a contribution to patient safety research, largely because there is a demand for understanding as well as measurement and prediction. Studying contributory factors in conjunction with the reporting process proper, should unearth both quantitative variables [e.g. error types], and qualitative phenomena [e.g. socio-cultural factors or blame]. The nature of the topic demands appropriately sensitive methods to encourage organizational and individual participation but also the safeguarding of participants should they decide to participate. It is apposite that Lawton and Parker (2002) suggested the future design of reporting systems might benefit from the principles of human error theory.

Having established a clear picture of human error theory, its application to health care including the essential role of taxonomies, and incident reporting both outside and inside health care, it is now appropriate to carry out a systematic review of the literature specific to drug errors and their reporting.

CHAPTER 3: SYSTEMATIC REVIEW OF CONTRIBUTORY FACTORS IN DRUG ERROR AND THEIR REPORTING

3.1 Introduction to the systematic review

The previous chapter detailed the theory underpinning human error in the context of drug errors, and the practice of error reporting both inside and outside health care. The epidemiology of drug errors was then discussed which was followed by an overview of the methodological issues in medical error research. The previous chapter finally focussed on the epistemological and ethical considerations for this study. The aim of this chapter is to summarise, appraise and communicate the results and implications of a range of selected, empirical studies which directly examine the contributory factors in drug error and their reporting.

The search strategy for the systematic review is presented and then, the review of empirical studies directly related to the contributory factors in drug error and the reporting of these errors. Figure 3.1 summarises the principal sections in this chapter. Finally, and by means of a conclusion to chapters 2 and 3, the arguments are made for a discrete study of the reporting of drug errors using particular methods, underpinned by the theoretical framework described previously, to better understand and develop the science of drug error reporting.

There has been a massive rise in the volume of patient safety research (Maillard et al, 1005, Brown et al 2006). However, the wide range of definitions evident in the reporting of drug errors, the so called ‘soft outcomes’ such as errors and adverse drug events (Morimoto et al 2004, p312), and the lack of randomised controlled trials directly linked to this type of research (as shall be seen), would not allow for a meta-analysis. Nevertheless, the empirical studies selected specific to the aim of this systematic review, will be accompanied by a qualitative commentary to allow an assessment of their quality.

Figure 3.1: Principal sections in systematic review

- Search strategy
- Review of empirical studies: contributory factors in medication errors
- Review of empirical studies: reporting medication errors
- Rationale for the study and chosen method

3.2 Systematic Review: Contributory factors in drug error, and drug error reporting

3.2.1 Search Strategy

Data bases

The data bases searched were:

MEDLINE

EMBASE

CINAHL

PSYCINFO

PHARMLINE

COCHRANE (www.cochranelibrary.com)

The databases were selected to cover both health care and psychology literature, a selection which was also carried out by Maidment et al, (2006) in their systematic review of drug errors in mental healthcare. Following discussion with the specialist librarian for Pharmacy at the University of Bradford, *PharmLine* was chosen as the pharmacy database due to its focus on medication management, pharmacy practice and prescribing for which it draws on 28 journals. However, the specifications in *Pharmline* did not allow the same level of analysis or synthesis with search terms.

3.2.1.1 Patient safety policy documents and grey literature

The patient safety organisations formed in the UK, USA, and Australia and their associated governmental or professionals organisations have produced numerous policy documents; some of which have provided critical comment on previous research studies and others which have informed subsequent studies. Consequently, the web sites linked to the National Patient Safety Agency (UK), National Patient Safety Foundation (USA), and the Australian Patient Safety Foundation (APSF) have also been searched.

3.2.1.2 Unpublished papers: higher degrees

To reduce the risk of publication bias, dissertations and theses registered for higher degrees which contained the terms 'contributory factors in medication/drug errors' and or reporting drug/medication errors were searched for using www.theses.com

It was clear that studies outside of health care informed patient safety initiatives (specifically error reporting), particularly from the field of aviation. To reduce the problem of missing such studies due to using health databases, references from extracted patient/healthcare safety papers that specifically drew on the application of aviation safety initiatives were also reviewed.

3.2.1.3 Piloting the strategy

Using Ovid, a search strategy was piloted in Medline, it being the most comprehensive of the electronic databases for medical and health care science journals. Following testing in Medline for both sensitivity and specificity, the strategy was then tried in a range of other databases to achieve the breadth of coverage necessary to identify relevant literature. The benchmark studies in medical error (Brennan et al 1991, Leape et al 1991, Wilson et al 1995, Thomas et al 2000, Vincent et al 2001) created the impetus for an ongoing series of research programmes. Subsequent reviews demonstrate a dearth of patient safety research prior to this. In their mapping of the patient safety literature, Westwood et al (2001)

included studies on medication errors, reporting systems, and organisational culture, but only cited healthcare studies from 1990 to the date of publication. A review of organisational factors on medical errors largely restricted their search to papers from 1990 Hoff et al (2004). A large scale systematic review for Health Canada (Baker and Norton, 2002), confirmed that the patient safety research base has been almost entirely generated from a series of studies conducted in the period between 1990 and 2000, headed by the landmark HMPS (Brennan et al 1990). It was consequently decided to limit the search period from 1985 to 2007; this strategy was vindicated in that Medline only identified 6 relevant studies between 1950 and 1985. The reference lists from the primary research papers retrieved were also searched to detect any missed studies.

3.2.1.4 Key words

Using OVID Medline to map subject headings, the key text words chosen to begin the search were: “medication error$”, “drug error$”, and “adverse event$”. “Medication error$” was found to be a thesaurus term and a Medical Education Subject Heading (MeSH). ‘Risk management’ was included as a MeSH heading as it includes incident reporting.

The key words from a research paper exploring ‘attitudes and barriers to incident reporting’ (Evans 2006) were then examined to identify new, associated terms. Specificity in retrieving papers on both the contributory factors in drug errors and reporting was threatened by the presence of generic risk management papers, studies of adverse drug reactions, and papers on reporting incidents on other discrete activities [e.g. blood transfusion]. The search record is available as Appendix item 3.

The final search terms were used to carry out 3 sequential searches:

1. Contributory/contributing/risk/ factors in medication errors/drug errors/near misses/adverse drug events (and relevant synonyms)

2. Above combined with incident reports/risk management
3. Incident reports/risk management combined with attitudes/motivation/incentives/barriers

For updates of new publications that matched the key words in the search strategy, alerts were set up via OVID, including 'in process' papers.

3.2.1.5 Exclusion criteria

1. Non-English language and non-human studies
2. Studies not described as classic papers, research papers, or systematic reviews
3. Papers based on contributory factors in adverse drug reactions and other non-preventable medication events/incidents
4. Papers based on studies of community or mental health settings
5. Papers based on generic error reporting systems

3.2.1.6 Inclusion Criteria

1. Research papers specific to drug errors and their risk/contributory factors/causation in [general] hospitals
2. Research papers specific to the barriers to drug error reporting schemes and the design and evaluation of such schemes in [general] hospitals

Table 3.1 shows the total number of papers retrieved from each data base, and those discarded. A total of 119 abstracts were reviewed in Medline, which led to a significant number being discarded (89). This was predominantly due to their lacking original data but also because, if they were empirical studies, they were based on data from non-hospital settings; the variable or outcome under scrutiny was an adverse drug reaction and *not* a drug error. The NCCMERP taxonomy (1998) was used to define drug error as it has been adopted by the DoH and NPSA, and is the operational definition for this study (see pages 29 and 31). Some papers were duplicated across data bases. The reference lists from the

research papers retrieved directly from the electronic databases allowed a generous retrieval of additional papers, some of which were included in the review. There was a very large volume of references generated from the word search in Pharmline but on inspection of the titles (and abstracts), most were opinion or non-research papers, and many papers focussed on error incidence.

Table 3.1: Total number of papers retrieved and discarded from each data base searched

Electronic Database searched	**References retrieved**	**Abstracts reviewed**	**Articles reviewed**	**Articles selected as eligible**
MEDLINE	303	119	30	30
Embase	279	18 (4 duplicates)	3	1
PsycInfo	177	18 (3 duplicates)	2	1
CINAHL	177	18 (3 duplicates)	2	1
Pharmline	1358* (Hits)	71 (4 duplicates)	4	4

For each study included, the key elements were tabulated where possible (Figure 3.2), using criteria modified from the NHS Centre for Dissemination and Reviews Report 4 (2001). The previous appraisal of the key methodological issues in error research demanded that each paper was also specifically reviewed for use of a theoretical framework, an error definition and any reliability checks. The nature of the selected papers was diverse in materials, measures and analysis. As such the papers were accompanied by a qualitative commentary concerning their methodological rigour rather than being quality graded or quantitatively synthesised; the latter, more reductionist strategy typically seen in systematic reviews of fixed design studies, such as randomised controlled trials. The critique of qualitative studies was informed by Giacomini and Cook (2000).

Figure 3.2: Key elements of selected studies [using criteria modified from the NHS Centre for reviews and dissemination]

- The specific population involved (patient group and setting)
- The variables under scrutiny (contributory factors in drug error, reporting schemes)
- The data collection method/intervention
- Analytic framework
- The findings and or outcome(s)
- Commentary on methodology and relevance to this study

The results of the review and their implications are now discussed with reference to the objectives of this study. The review of articles specific to contributory factors is presented prior to the review of articles specific to drug error reporting. The studies concerning contributory factors are discussed according to their stage in the delivery process, and in the standard order: prescribing, dispensing, and administration, a model also used by Miller et al (2007) in another systematic review. The results are given followed by a brief discussion and conclusion.

3.3 Contributory factors in drug error

Four reviews of contributory factors were identified from the search - specifically focussed on drug administration errors (O'Shea 1999, Pape 2001, Armitage & Knapman 2003, Carlton & Blegen 2006). However, as these were not systematic reviews, they were not included.

The studies included in this first review were tabulated and are shown in Appendix item 4, a total of 26 papers were included. Each study is individually tabulated mindful of the issues raised in Chapter 2, Section 2.9, thus offering detail on study design, theoretical frameworks, error classification, measures, analysis, findings, weaknesses and relevance. Adverse drug events and errors were clearly defined in 15 papers. Of these, five authors defined error by error type, [e.g. wrong dose, drug omission etc.], rather than using a cognitive (or process) definition such as that offered by Reason (1990). Explicit theoretical frameworks were less common still, having been cited in only 9 of the papers; 5 of these being based on Reason's human error and accident causation theories (Beso et al, Dean et al, Leape et al, Sanghera et al, Taxis & Barber). Hintong et al (2005) based their study on the earlier theories of Rasmussen & Jensen (1974). Of the studies selected, 10 collected data from university teaching hospitals, and 12 collected data from more than one centre. Methods of data collection differed considerably, however there was a discernable pattern as expected: prescribing errors were often studied by case note and chart review, and administration errors by a much broader range of

methods including quantitative and qualitative observations.

The majority of studies were then focussed on a single stage in the delivery of drugs to a patient [e.g. prescribing], or as in Leape et al's study which examined each phase, divided their findings accordingly. However, some studies did not discriminate between phases, and consequently their relevant findings are considered separately. Bates et al (1999) conducted a large twin-centred, randomised, nested case control study to analyse the patient factors in ADEs. After controlling for level of care and length of stay; poly-pharmacy, age and impaired physiology were not statistically significant factors. Sanghera et al (2007) carried out a traditional qualitative study, although there were obvious threats to validity: a resident pharmacist identified errors by chart review and incident reports, and then interviewed the staff concerned; and the study was carried out in one intensive care unit with a small but mixed discipline sample of 13 medical and nursing staff. Malpass et al (1999a) analysed incident reports from an existing data bases and although their conclusion were important to this study, they did not generate a detailed analysis of contributory factors.

Bates et al (1999) concluded that systems factors (and their prevention) should be investigated in preference to individual patient factors. Sanghera et al's study was more detailed and used human error theory. They suggested slips and mistakes were quite common alongside error producing conditions such as poor communication and knowledge deficit. Latent failures included inconsistency and diffusion of responsibility in double checking drugs, and administering drugs without a prescription.

The remaining results of the review and their implications are discussed below under the headings of: prescribing, dispensing, and administration; a model also used by Miller et al (2007) in their systematic review of paediatric drug errors. Table 3.2 tabulates the frequency of contributory factors from this review, across all stages of drug delivery.

Table 3.2: Contributory factors in drug errors by stage of drug delivery process: factors identified in three or more studies in systematic review

Contributory factors	Prescribing	Dispensing	Administration	Total number of studies citing this factor
Lack of knowledge (of drug and or patient)	Dean et al (2002b) Leape et al (1995) Lesar et al (1997) Sanghera et al (2007)	Beso et al (2005) Leape et al (1995)	Gladstone et al (1995) Hand & Barber (2000) Leape et al (1995) Sanghera et al (2007) Tang et al (2007) Taxis & Barber (2003) Wakefield et al (1996)	13
Interruptions & distractions	Dean et al (2002b)	Beso et al (2005) Peterson et al (1999)	Gladstone et al (1995) Gordon et al (2006) Hand & Barber (2000) Hartley & Dhillon (1998) Mrayyan et al (2007) Tang et al (2007) Taxis & Barber (2003) Wakefield et al (1996)	12
Communication problem with colleagues/fellow professionals	Leape et al (1995) Dean et al (2002b) Sanghera et al (2007)	Leape et al (1995)	Hartley & Dhillon (1998) Hintong et al (2005) Kazoaka et al (2007) Leape et al (1995) Sanghera et al (2007) Taxis & Barber (2003)	10
Lack of experience	Lesar et al (1990) Sanghera et al (2007)	Bond & Raehl (2001) Roberts et al (2002)	Hand & Barber (2000) Kozer et al (2002) Schulmeister (1999) Sanghera et al (2007) Tang et al (2007) Hintong et al (2005)	10
Slips, lapses, mistakes	Dean et al (2002b) Leape et al (1995) Sanghera et al (2007)	Beso et al (2005)	Gladstone et al (1995) Hintong et al (2005) Leape et al (1995) Sanghera et al (2007) Taxis & Barber (2003)	9
Staffing	Dean et al (2002b) Malpass et al (1999)	Beso et al (2005), Bond & Raehl (2001) Malpass et al (1999) Roberts et al (2002)	Hand & Barber (2000) Malpass et al (1999) Schulmeister (1999)	9
Failure to check or poor check	Leape et al (1995) Sanghera et al (2007)	Leape et al (1995)	Gladstone et al (1995) Gordon et al (2006) Leape et al (1995) Sanghera et al (2007) Tang et al (2007)	8
Rule violations	Dean et al (2002b) Leape et al (1995) Sanghera et al (2007)		Gladstone et al (1995) Hintong et al (2005) Sanghera et al (2007) Taxis & Barber (2003)	7
Workload	Dean et al (2002b)	Roberts et al (2002) Peterson et al (1999)	Gladstone et al (1995) Tang et al (2007) Tissot et al (2003)	6
Lookalike/soundalike drugs	Lesar et al (1997), Furukawa et al (2000)	Beso et al (2005), Furukawa et al (2000) Peterson et al (1999)	Furukawa et al (2000)	6
Illegible prescription		Roberts et al (2002)	Gladstone et al (1995) Tissot et al (2003) Wakefield et al (1996) Schulmeister et al (1999)	5
Poor stocking	Leape et al (1995) Malpass et al (1999)	Malpass et al (1999)	Malpass et al (1999)	4
Fatigue	Dean et al (2002b)	Peterson et al (1999)	Gladstone et al (1995) Gordon et al (2006)	4
Patient characteristics	Lesar et al (1997)		Prot et al (2005) Tang et al (2007) Furukawa et al (2000)	4
Pace of work	Dean et al (2002b)	Beso et al (2005) Bond & Raehl (2001)		3
Miscalculation	Lesar et al (1997)		Gladstone et al (1995) Hand & Barber (2000)	3
Lack of time		Beso et al (2005), Bond & Raehl (2001)	Hintong et al (2005)	3
Device misuse			Leape et al (1995), Mrayyan et al 2007), Taxis & Barber (2003)	3

Other factors (Cited twice): time of day (Lesar et al 1990, Hartley & Dhillon 1998), reduced risk awareness (Dean et al 2002b, Taxis & Barber 2003), low value attributed to prescribing/admin. (Dean et al 2002b, Taxis & Barber 2003), poor labelling (Gordon et al 2006, Mrayyan et al (2007). Cited once: poor light/excess noise (Hartley & Dhillon 1998), syringe swap (Gordon et al 2006), lack of guidance (Beso et al 2005), monotony of practice (Sanghera et al 2007), complicated prescription (Tang et al 2007), Lack of protocol (Tissot et al 2003), chart design (Hartley & Dhillon 1998), perceived inevitability of error (Beso et al 2005), poor role models (Taxis & Barber 2003), poor feedback from reported errors (Sanghera et al 2007), Stress (Schulmeister 1999)

3.3.1 Prescribing

The studies reviewed employed single methods, excepting Leape et al (1995) who employed case note review with interviews, and Dean et al (2002) who used case note review but only for additional information. Chart review was the predominant method (Kozer et al 2002, Lesar et al 1990, 1997). Retrospective analysis of incident reports was not employed.

Although case note review was also used by Leape et al (1995) - this was to principally identify errors - confidential qualitative interviews were judged necessary to reveal contributory factors. Leape et al and Dean et al both appeared to use strongly structured interview schedules, and their data were analysed using human error theories (Reason 1990, 1997). However, there was a general sense that the participants were likely to have produced data which would *not* create a negative self-image. Leape et al's study is frequently cited, and although the authors question its generalisability to district hospitals, the theoretical framework was rigorously applied, reliability checks were integral to the data analysis, and the identified factors were described as having considerable face validity. Leape et al used multi-disciplinary panels to classify contributory factors while Dean et al employed an independent coding check as part of their qualitative analysis. Kozer et al subjected 10% of their sample to independent reliability checks, as did Lesar et al (1997) who found unanimity of agreement in 97% of cases.

Importantly, the contributory factors in prescribing errors were judged by Leape at al and Dean et al as being multiple; including technical, cognitive and socio-cultural factors, bearing out Reason's theories around concatenation. While Leape et al identified poor monitoring and slips and lapses as common factors, rule violations were also dominant, which shared common ground with Dean et al who, although having collected data from just one site, suggested that there was a low risk awareness concerning drug errors and a low value attributed to the act of

prescribing. Dean et al's participants also commonly cited workload and pace of work as influential factors, but also deficient knowledge. The two studies by Lesar et al (1990, 1997) suggested that inexperience is a key factor, which may according to Kozer (2002), be exacerbated by patient factors such as level of patient illness – although Kozer's study was specific to a paediatric accident & emergency department.

3.3.2 Dispensing

Dispensing errors have received far less attention in the literature. Of the dedicated dispensing studies, one used mixed methods (Beso et al 2005), two used postal surveys (Peterson et al 1999, Bond & Raehl 2001), and one was a simple, retrospective analyses of adverse events using incident reports (Roberts et al 2002). In the mixed methods study, a record was kept of dispensing errors from the final departmental check and following an error, confidential qualitative interviews were employed to elucidate the contributory factors. The interviews yielded a range of contributory factors but were strongly structured, Beso et al having used a list of contributory factors upon which they based their questions. Again it is possible that the interview participants were likely to produce data which would *not* create a negative self-image. Bond & Raehl employed a questionnaire which had been subjected to multiple testing, but only achieved a 39% response rate. Nevertheless, it yielded 517 responses from hospital pharmacies.

The common contributory factors in dispensing errors are: slips, faulty checking, pace of work (increased number of orders to process), interruptions, poor stock control, and lookalike/soundalike drug names. The data from the incident reporting scheme identified similar factors but also inexperience and poor transcription. It is possible that working conditions in the pharmacy department in combination with the repetitive nature of the process, and product, may have a particular influence on error.

3.3.3 Administration errors

Dedicated studies of the contributory factors in administration errors were more numerous than either prescribing or dispensing studies. Of the dedicated administration studies, questionnaires were used in six studies; observation in four studies; interviews, and incident report analysis in two studies. Only Leape et al (1995) drew on case note review but as discussed earlier, this was a generic study which included administration errors, and also employed interviews. In fact mixed methods were only used in one dedicated administration study, by Gladstone (1995). Documenting the broader threats to validity, Gladstone cautioned that their interview participants had been recruited via their managers, undoubtedly mindful of the sensitivities of both error research and the organisation in which it is carried out.

Closer inspection showed that two types of observation were used – disguised and non-disguised. The choice of observation appeared to be dependent on the level of concern about the Hawthorne effect, but it has been argued elsewhere that the some of these concerns may be somewhat exaggerated, especially if a more sustained period of qualitative observation is mounted (Armitage & Hodgson 2004). Additionally, it might be considered inappropriate *not* to fully inform the observed about the aims of such studies when many governmental agencies are simultaneously striving to develop open and transparent cultures (Armitage & Hodgson 2004). Other more general limitations in the drug administration studies were valid sampling [e.g. of observational periods]; and in relation to incident report analysis: that the number of reports analysed was small and often held little data.

The common contributory factors in drug administration errors do not appear to differ substantially according to the method of data collection, and in relation to observation - there was common ground - whether the analysis was quantitative or qualitative. However, Prot et al (2005) and Tissot et al (2003) who both used

multiple regression models differed in their focus; Prot et al's work was based solely in paediatrics, whereas Tissot et al, in spite of a smaller sample, compared two very different specialities and was perhaps more generalisable.

The use of clear theoretical frameworks in some studies - especially human error theory - again demonstrated the multi-faceted, multi-factorial nature of administration errors as in prescribing and dispensing errors. At the sharp end it would appear that poor checking and misidentification of drugs is an abundant factor. Error producing conditions included increased workload, skill mix deficiencies, as well as interruptions which were commonly cited allied to workload. At a broader systems level, studies based on interviews show that poor knowledge is an issue, and interestingly, observational studies might indicate that skill-based errors such as poor checking may emanate from cultural factors such as problematic intra-disciplinary and inter-disciplinary communication, and a lack of perceived risk. A collective analysis of the factors from all the studies also suggests that the nature of drug administration errors, as explained by nurses, indicates that some of the factors are also inherited from problematic dispensing and prescribing processes, [e.g. illegible prescriptions]. Finally, for the participants in Sanghera's study the lack of feedback from poor reporting was seen to be a contributory factor.

3.4 Drug error reporting

The second part of the review considers papers specific to drug error reporting schemes in hospital-based health care, including the barriers, and staff attitudes therein. The specific empirical studies selected are discussed on the basis of their specific focus which was the:

1. Attitudes and barriers to drug error reporting
2. Design/implementation/evaluation of drug error reporting schemes

The studies included in this part of the review were tabulated and are shown in

Appendix item 5. A total of 19 papers were included in the review. The diversity of method seen in the studies of contributory factors above was also evident in the studies of drug error reporting. Moreover, to address the above focus, the papers were equally eclectic in their aims; however it is argued they offer an important contribution to this knowledge base. No literature reviews were found. Drug errors were defined in six papers, and adverse events in the two papers. Interestingly these definitions were all different. Of the studies lacking definition, it was perhaps inappropriate for authors such as Kane-Gill et al (2006) to define drug error as one of the aims of the study was to actually develop a participant definition. Confusingly, Dejong (1998) defined an error as an event for which an occurrence report existed, perhaps inadvertently promoting a theoretical free for all. Finally, the participants' responses in two studies (Wakefield et al 1996b, Sanghera et al 2007) suggested that difficulties in reporting arose from not knowing whether an error had actually occurred.

As in the prior review of contributory factors, theoretical frameworks were less common still – evident in just one study (Sanghera et al 2007) – where human error theory structured the analysis. This seems ironic as the data was sometimes thought to be ambiguous, which was thought to militate against a more critical appraisal (Desikan et al 2004). Of the studies selected, four were carried out in university teaching hospitals, and seven in acute hospitals; eight were multi-centred. The larger multi-centred studies employed survey methods – with self administered questionnaires. Although Smetzer et al's study examined the broader topic of medicines safety, the specific focus on reporting, and blame as a barrier to reporting allowed its inclusion. A total of eight surveys were carried out, the response rates varied from 84% (Crawford et al 2003) to three with less than 30% (Smetzer et al 2003, Wakefield et al 1996, Kane-Gill et al 2006). Potylicki et al (2006) and Wakefield et al (1999a &1999b, 2001) did not report a response rate. Seven studies employed retrospective incident report review, and four studies

utilised qualitative interviews (including one study with focus groups). Multiple methods were used in only one study. The greatest volume of data concerning the attitudes and barriers to reporting emanated from the qualitative studies where data was collected from interviews (Hand & Barber 2000, McCardle et al 2003, Sanghera et al 2007). The free text data in incident reports was not analysed, despite some papers explicitly aiming to improve such data (Dejong et al 1998).

3.4.1 Attitudes and barriers to drug error reporting

Improving drug error reporting, especially reporting rates is not easily accomplished (Cullen et al 1995). Smetzer et al's large scale North American survey, despite relying on institutional self-assessment and having a low response rate demonstrated that staff felt under confident about reporting errors. The most common barriers to drug error reporting have been identified in several studies. However, it is apparent that practitioners may be selective in their reporting habits, tending to report serious errors rather than minor errors or near misses (Cullen et al 1995, Hand and Barber 2000) – a problem may be exacerbated by some practitioners not knowing what to report, or a lack of agreement between individuals on what to report (Wakefield et al 1999b).

The trends in general incident reporting by profession are similar to those in drug error reporting, doctors being the most reluctant, and nurses the most prolific (Ashcroft et al 2003, Wilson et al 1998, Furukawa et al 2003, Miller et al 2006), additionally there may also be unit-based differences where the organisational subcultures mentioned in the previous chapter (Carroll & Quijada, 2004) actually impact on reporting (Wakefield et al 2001, Desikan et al 2004).

Consistent across professions and units or specialities is however, the view that reporting is a time consuming process (Wakefield et al 1996, 1999b; Hand and Barber 2000, McCardle et al 2003, Sanghera et al 2007), and that staff frustration is compounded by a lack of feedback (Dejong et al 1998). It would also appear from

the qualitative study of doctors' views of drug error reporting (McArdle et al 2003) that there is a reluctance to use organisation-wide schemes in preference to local discussion and resolution, overlapping with some of the findings related to generic incident reporting (Waring 2005).

Fear of blame appears to be the major barrier (Wakefield et al 1996, 1999b; Hand & Barber 2000, Smetzer et al 2003, Sanghera et al 2007). However, Hand and Barber also implied that nurses, by being more individually focussed (rather than systems focussed) might inadvertently propagate the blame culture. That blame seems to be discriminating, for example, nurses are more likely to be blamed than doctors (Hand and Barber 2000) may also fuel inter-professional tensions. It is then perhaps inappropriate that some studies have solely focussed on nurses' or pharmacists' reporting behaviours in assessing a given scheme and not medical staff (Dejong et al 1998, Jones et al 2006, Miller et al 2006). The non-punitive scheme highlighted by Potylicki et al (2006) implies that reporting rates (especially of near misses) are likely to rise in the absence of [inappropriate] blame.

Conversely, according to Crawford et al's large scale survey of 169 North American hospitals, only a 24 hour pharmacy service appeared to be a statistically significant factor in increasing reporting. The findings from one study, albeit sizeable, should not however be seen as conclusive, especially as the profession of the respondents was not identified and the survey despite been multi-centred was self-administered using a convenience sample.

3.4.2 Design/implementation/evaluation of drug error reporting schemes

The systematic evaluation of drug error reporting schemes not only provides data that can potentially inform the design of improved systems but it also serves to dispel some of the myths around reporting, perhaps the key myth being that an increased reporting rate does not mean an increased error rate (Crawford et al 2003). Furthermore it is impossible to report all drug errors (Cullen et al 1995).

Miller et al (2006), following their detailed assessment of the accuracy of an electronic reporting scheme, asserted that this mode of reporting reduces the administrative burden, and allows easier and quicker feedback, however they did not comment on the recording or collation of contributory factors. It was also apparent that some schemes lacked conceptual clarity with contributory factors (Desikan et al 2004, Jones et al 2006), akin to the lack of theoretical underpinning in the NCCMERP (1998) taxonomy. Miller et al (2006) advocated a mixed structure of free text and tick boxes to gain more information.

In summary the review of studies specific to drug error reporting schemes suggest:

- Reporters are not always aware of how to define a drug error and this affects their reporting
- Near misses are less likely to be reported than adverse events despite their learning potential
- Reporting rates vary by profession
- Reporting is characterised by cumbersome processes and poor feedback to reporters – electronic reporting may improve these problems
- Reporting may result in individual blame for reporters
- Myths surround reporting such as increased reporting by a unit means the error rate is also increasing
- Reporting schemes lack theoretical underpinning and clarity

3.5 Conclusion

Although there was no quality grading in this review, it is argued that the alternative qualitative commentary provided sufficient compensatory information on the standard of studies included. From the commentaries it is apparent that some of the studies lacked methodological rigour, but their findings nevertheless held value in appraising the utility of various methods.

The results of the systematic review should then be considered in the light of the predominant methodological issues in medical error research discussed earlier: the use of clear and consistent operational definitions; sensitivity of methods for error detection (specifically the sensitivity to identify contributory factors); and establishing [inter-rater] reliability. The wide range of definitions, and in some cases, lack of definition, is a fundamental challenge to accurate measurement. Consequently, contributory factors may vary accordingly; a variance that might be increased in any qualitative analysis by practitioners' differing perceptions of the factors involved. It is then contended that measures of inter-rater reliability should be generally adopted similar to those of Leape et al (1995), based on independent checks for error, error type, and contributory factors. Comparative checks for qualitative studies should include independent checks on coding and category formation.

From most of the studies of contributory factors, both those which employed theoretical frameworks, for example, Leape et al 1995, Dean et al (2002b), and those which did not (Gladstone 1995, Tang et al 2007, Tissot et al, 2003), it is clear that single errors result from multiple factors reflecting the maxims of human error theory discussed in Chapter 2. Lack of knowledge, interruptions and distractions, poor communication, active failures and inexperience are predominant problems. Organisational factors or latent conditions are less commonly cited but this may be related to methods of data collection.

It is then argued that human error theory is a suitable theoretical framework for teasing out and logically discussing causation. It is also useful in confirming some of the paradoxes in causation highlighted here, for example, more experienced practitioners seem more ambivalent about drug checking (Kazoaka et al 2007), and staff working less hours might be more likely to make errors (Wakefield et al 1996). It has been suggested that further research should be carried out to understand causation more fully (Prot et al 2005). However, in relation to this study, causation

should be examined in conjunction with error reporting, as the principle raison d'etre of reporting is understanding and learning (Furokawa et al 2003), a point heavily endorsed by the NPSA (2004, 2005).

There are numerous barriers to reporting, many of which are replicated across different clinical settings. Fear of organisational retribution, seems all pervasive but it may be symptomatic of a general inclination towards an individual rather than systems approach to error which clearly requires exploration. It would also seem reasonable to argue that the design of reporting schemes have often lacked the ability to enthuse the users or gather effective data, thus limiting organisational learning. A more detailed understanding of reporting cultures would then be helpful to develop a user-friendly scheme, but unlike some of the studies here (Cullen et al 1995, Dejong et al 1998, Jones et al 2006) doctors' views alongside pharmacists and nurses, should also be collected. Their views on the practicalities of reporting would also be valuable. Retrospective report review alone yielded less rich data than the interview based studies but the lack of analytic frameworks in some studies (Desikan et al 2004, Roberts et al 2002), and the methods used, might have further reduced the potential yield. Nevertheless, some of the report reviews did provide useful information on improving reporting such as considering anonymity (Furukawa et al 2000), listing contributory factors as part of a specific drug error reporting scheme (Dejong et al 1998), and ensuring feedback (Wakefield et al 1999b). Unsurprisingly, Malpass et al (1999a) have also asserted, following their large scale review of reported adverse events, that studies of drug errors and their consequences demand a mixed methods approach. There is a clear overlap between the recommendations for improvement suggested by those who have studied drug error reporting schemes and the generic schemes referred to in the previous chapter.

The review findings suggest the need for a detailed study of those who have somehow experienced or reported drug errors, but from a multi-disciplinary sample

to avoid fragmenting the business of providing drugs to patients and uncover the multi-professional interactions that might facilitate error (Hintong et al 2005) and even block reporting. Such data is more likely to arise from methods which can sustain complete confidentiality and allow the researcher to support the participants to speak of their own vulnerabilities. It can be seen that questionnaires, especially those self-administered (another source of bias, Orser et al 2001), have *not* produced consistently high response rates. Qualitative interviews however, especially if underpinned by human error theory - have supplied a rich stream of contextual data - often lacking in questionnaire data but also that based on observation. While volunteer samples seem to be the most feasible and ethical approaches to recruiting participants, reducing the impact of participants avoiding a negative self-image is a challenge. As a key objective of this study is to develop an enhanced reporting scheme, data should then first be collected from the existing scheme to evaluate its strengths and weaknesses, providing an orientation for any qualitative interviews, but also ultimately, to act as a comparator to the enhanced scheme.

This study will adopt the definition of drug error discussed earlier, but in tandem with human error theory to further advance a clearer understanding of the data.

Additionally, the findings from the systematic reviews will provide a theoretical base for any future reporting scheme designed to alert practitioners to the common contributory factors in drug error and how such a scheme might encourage reporting, while also improving its quality.

CHAPTER 4: METHOD FOR THE INCIDENT REPORT OR DOCUMENTARY ANALYSIS (STAGE 1)

4.1 Introduction

As discussed in the introduction (p2), the study is sequential in design. The findings from the documentary analysis in stage one will specifically inform the interview schedule (stage two), as well as expanding and appraising the dominant assumptions and propositions which emerge from the interview data analysis. Moreover, both the stage one and stage two data, in conjunction with the findings from the systematic review, will inform the development of the enhanced reporting scheme. Finally, all three stages of the study will collectively support the final recommendations concerning drug error reporting. This chapter will describe the data collection and analysis process employed for the retrospective analysis of incident reports pertaining to drug errors. Following an introduction which includes a description of the research setting, this chapter is divided into the following sections: sample; access; materials and measures; procedure; and analysis.

4.2 Research Setting

The setting for this study was a large teaching hospital foundation trust in the North of England. The trust enjoys a reputation of being at the leading edge of clinical governance developments and has received recognition for this from the Commission for Health Improvement. A recently commissioned Institute for Health Research has opened on the principle hospital site, and embarked on a dedicated programme of quality and safety research.

It is located in one of the most deprived health communities in the United Kingdom and where 20% of the population originate from South Asia. The trust has just over 1,000 beds with average bed occupancy of more than 80%. It employs

approximately 5,000 staff. At the commencement of the study, it was estimated that 800,000 items are dispensed by the pharmacy each year (Dobrzanski et al 2002). Particular pharmacy interventions around prescription improvement have included enhancing the Institute for Health Improvement trigger list to identify potential adverse events, standardizing prescription charts, and improving patient information.

4.2.1 Incident reporting methods in the setting

From 1995 to 1999 the style of incident report was largely based on a *tick the box* approach. The design of these reports appeared to be strongly influenced by the concept of health and safety in the work place, [i.e. the threat of non-clinical accidents to staff (and to patients), injuries from sharp objects, exposure to harmful agents, being struck by a moving object]. Description of the incident did however include the term 'near miss' as a tick box option. Reporters were asked who was directly affected by the incident and how; and a number of boxes were offered to identify the sort of injury [e.g. abrasion, amputation, fracture etc.]. Causes were listed, again as tick the box options, [e.g. 'fall from height, contact with hot object, exposure to biological agent]. Iatrogenic patient harm was not considered. A very small text box was provided for reporters' free text descriptions of circumstances. In the case of patients sustaining injuries from an accident, staff members were also asked if relatives had been informed. From 1998, all completed incident report forms were not kept on the wards but despatched to the Risk Management Department and subsequently archived. Two further forms emerged later in 1999, these were very similar to the earlier form other than having an enlarged free text box titled 'Circumstances' and an additional section titled 'Action Taken'. In 2000 the existing style of scannable incident reporting was introduced which largely removed the tick box options, but included three free text boxes: 'circumstances', 'underlying causes', and 'action to prevent recurrence'. This form moved away from a staff-centred accident notification model towards one of patient-centred risk

management. Severity of the incident outcome had to be graded, as had likelihood of recurrence, and the number of people involved. Consideration was given to how the documentary changes above might have influenced the reporter's approach to completion over the 5 year period studied. The changes described broadly ran in parallel with the increasing national and international awareness of medical error which would likely result in increased reporting. Additionally, the hospital staff had also experienced the consequences of a catastrophic adverse drug event in 2001 (national publicity, formal inquiry, legal action) where a previously well patient had died as a direct result of a drug error, which may have had a further effect on the rate of drug error reporting.

4.3 Sampling

A sample of all incident reports that were coded as drug errors in their generic reporting system for the previous 5 years (1999-2003) was provided by the trust (n=2506). This 5 year period also spanned the tail end of the staff centred reporting model and introduction of the patient-centred or clinical incident report. In order to systematise the data collection process a data extraction tool was constructed (Figure 4.1) which will be discussed further under Materials and Measures. To decide on the final sampling frame, the data extraction tool was piloted on ten randomly selected incidents from 1999 and the time spent on data extraction for each incident recorded.

A pilot review of 10 incidents took 1 hour 38 minutes, excluding gaining access to the archives and finding the files which were indexed by date but in separate Lever Arch files in individual filing cabinets. At this rate, it would have taken at least 408 hours or about 10 weeks to review the entire sum of submitted reports (approximately 2500). Consequently it was decided to extract a 50% random sample (n=1253), all the incident report file numbers were entered in a database and randomised using SPSS (Version 11.5). The concept of saturation (Morse

1995) was not employed, which might have curtailed the sampling process prior to reviewing all 1253 reports; instead, a sustained analysis was carried out. It was not apparent at the outset that the sample contained blood transfusion errors which, because they were not drug errors, were removed from all analyses except reporting rates by clinical location where their inclusion allowed a broader picture of the staff's inclination to report.

4.3.1 Access

The archived incident reports were kept in a locked archive. Withdrawing originals or copies of the incident reports to be reviewed from the archive was not permitted. This demanded reading them within the archive and transferring their anonymised contents into a personal laptop computer. The laptop computer remained in the author's possession in a locked room at his home address, with all files backed up on a portable hard drive in the same location. Local Research Ethics Committee approval was sought and given based on the above access procedure (see Appendix item 7).

4.4 Materials and measures

Definitive drug errors were classified according to the definition provided by the National Coordinating Council for Medication Error Reporting and Prevention or NCCMERP (1998), which is also utilised by the NPSA (DoH 2004, p20):

'a medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health professional, patient or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature: compounding; dispensing; distribution; administration; education, monitoring and use' (NCCMERP, 1999).

The Department of Health (DoH) definitions of near miss and adverse [drug] event were used which are respectively:

'an error that does not result in patient harm or an error with the potential for harm but is detected before reaching the patient' (DoH 2004, p21)

'An event or omission during the process of providing a drug to a patient that causes a physical or psychological injury' (adapted from the previous definition of an adverse event, DoH, 2000a.

Incident reports based on adverse drug reactions were not included in the sample unless they had occurred when it was already known by the organisation that the patient concerned would have an adverse reaction to the drug in question and it was documented that the drug should not be given. Incidents concerning the transfusion of blood products were also excluded as blood is not defined as a medication.

The collection of quantitative variables was principally organised by a data extraction tool which was designed following an assessment of the structure and content of the existing incident report form (Figure 4.1).

Figure 4.1: data extraction tool

Definitive drug error Y/N	Protagonist by profession
Patient involvement Y/N	Reporter by profession
Patient age	Relatives informed
Patient gender	Near miss Y/N
Clinical Location	Patient Harm Y/N
Date of report	Drug error type
Report Time	Contributory factor Y/N [If Yes, identify type and frequency]

The qualitative data was subjected to a content analysis designed for the analysis of formal documents (Holsti 1969), and cited by Scott (1990) in a more recent

detailed guide on analysing documents for social research. The terminological language used in the NCCMERP taxonomy of error types and contributory factors guided the classification process for error types and contributory factors.

4.5 Procedure

Not all of the quantitative variables identified in the data extraction tool were available in their designated boxes on the report form. Some were absent due to reporter error, and others had to be drawn from the free text as they were not part of any mandatory field on what was a generic incident report form [e.g. whether the error resulted in a near miss]. All variables that could be counted were transposed from the incident reports on to a Microsoft Excel spreadsheet. The auto-filter facility allowed quick and easy navigation of the spreadsheet. Where possible, standard binary labels were used [i.e. 1 or 0] to symbolise yes or no as in the classification of near misses which were then easily totalled. Tables and charts were prepared using Chart Wizard.

The qualitative data was collected from the three free text boxes which formed the three stages of the reporting process:

1. Circumstances
2. Cause
3. Action Taken

The free text was retyped verbatim into a Microsoft word document. A consecutive numbering system was used to identify each individual report's text and organised into the three stages described above. A colour coding system was used to identify particular styles of content, [e.g. when there was no coherent relationship between circumstances and cause, or cause and action taken].

Error types and contributory factors could only be found in the free text. When type and or factor were identifiable the adjacent margins were annotated accordingly. Whenever possible, the terminology in the NCCMERP (1998) classification system

of error types and contributory factors was used. If however, existing published terminology wasn't available or suitable, new terminology was employed based on the original data; for example: communication systems between health care practitioners was split for specificity into 'verbal communication and other communication systems' and 'written miscommunication'.

4.6 Analysis

4.6.1 Quantitative

All numerical data were analysed using descriptive statistics. The variables and their corresponding statistical analysis are shown in table 4.1.

Table 4.1: Quantitative variables and descriptive statistics used

Quantitative variable	**Descriptive statistics used**
Definitive drug error Y/N	Total number of definitive drug errors by year and percentage of all reported drug incidents that were errors
Patient involvement Y/N	Total number and percentage of drug errors where patients involved
Patient age	Frequency by 10 year intervals
Patient gender	Frequency and percentage by gender
Clinical Location	Frequency and percentage by speciality
Date of report	Frequency by month
Report Time	Frequency by hour periods
Protagonist by profession	Frequency and percentage of total population
Reporter by profession	Frequency and percentage of total population
Relatives informed Y/N	Total number and percentage of drug errors where relatives informed and linked to speciality
Near miss Y/N	Total number and percentage of near misses
Patient Harm Y/N	Total number and percentage of drug errors where patients were harmed
Drug error type	Total number of definitive drug errors reports where error type present, and drug error type by frequency and percentage of drug errors reported
Contributory factor Y/N [If Yes, identify type and frequency]	Total number of definitive drug errors reports with contributory factors and where present, contributory factors by frequency and percentage of drug errors reported

If particular trends were seen to be evident, further analysis would be carried out. If there was a particular prevalence of one error type, then the frequency of this error type would also be compared to clinical location and time period. The data were also explored to examine if there was any relationship between error types and contributory factors.

To assess inter-rater reliability, a random sample of 10% of all the incident reports reviewed (n= 125) were subjected to co-rating as implemented before in two studies of the frequency and relationship between drug errors and adverse drug events (Bates et al 1995, Kaushal et al 2001). Cohen's Kappa (Cohen 1960) was chosen as it has been previously used in rating reported adverse events (Cullen et al 1995). Kappa measures the difference between observed and expected agreement with nominal data, so a researcher can adjust the observed level of agreement by the proportion expected by chance alone.

Although the inter-rating process here was carried out in 2005, it mirrored the (subsequent) recommendations of Kunac et al (2006) in their classification of medication related events in paediatrics - independent review would be undertaken by a minimum of two other independent reviewers - in this case the study supervisors.

Four items were co-rated, two of which were 'Yes/No' decisions:

1. Definitive drug error (Y/N)
2. Near miss or not (Y/N)
3. Error type: one or more of 14 choices
4. Contributory factor: one or more of 24 choices

The independent reviewers were given a printed guide (Appendix item 8). This included: the NCCMERP definition of a drug error, a list of drug error types, a list of contributory factors, and an explanation of the term 'rule violation'. Any contributory factors stemming directly from the NCCMERP taxonomy and thought to be

ambiguous were also explained, [e.g. 'performance deficit']. The reviewers co-rated together without interruptions, and resolved any differences in opinion at that time.

The greater the number of nominal options for co-raters, the lower the kappa is likely to be, as there are more ways to disagree. Consequently, it was decided that contingency tables would be constructed to show agreement concerning error types and contributory factors where there were numerous options for each. A third round of co-rating (the researcher together with the co-raters) was not carried out as it was not considered beneficial to the study outcomes to reach consensus. Any findings that provoked uncertainty or clarification would be considered as items in the forthcoming interview schedule.

4.6.2 Qualitative (content analysis)

Holsti (1969) originally designed his content analysis (CA) framework for the analysis of mass communications, but it is transferable to other domains such as official documents. The unit of analysis is words, sentences or paragraphs; and as the analytic framework conforms to a sociological tradition it must be a theoretically driven process, here it was largely driven by human error theory. The framework is not a rigid 'cookbook' of instructions (Holsti, p136-7). Importantly, the counting of units, such as error types is not precluded by Holsti, but he has cautioned readers against needless counting which can induce a false precision. The counting here was to demonstrate the total numbers/percentages of drug errors by type and their contributory factors. There were two aims in the content analysis which are shown in Figure 4.2. The objectives are also shown; number 1 (a, b, and c) have been modified from the original objectives defined by Holsti. Holsti also urged specific comparisons to be made within the data which was carried out here; he described documentary content as a 'message' (p50), and asked for comparisons of messages over time, in different situations and across different audiences.

Figure 4.2: Aims of the content analysis (Modified from Holsti, 1969).

1. **Examine the context of any contributory factors and that of the allied reporting process**
   Objectives
   a) Describe the key characteristics of [drug error reports] as communications
   b) Make inferences about the antecedents of [these] communications
   c) Make inferences about the effects of communication [between the protagonist and management]
   d) Develop a semi-structured interview scheduled for the subsequent qualitative interviews based on questions raised from this analysis

2. **Extract error types and contributory factors**
   Objective
   Systematically list error types and contributory factors using an established taxonomy for a quantitative analysis

The process was distilled into 5 stages (Figure 4.3) which facilitated a systematic approach to the selection of categories, providing a reference for their source and a rationale for any construction.

Figure 4.3: Five stages in the process of content analysis (Holsti 1969, p50)

1. List explicit criteria for the sampling and selection of extracts employed for concept illustration
2. Construct coded categories of meaning based upon rigorous and replicable procedures
3. Provide clear definitions for each category with underpinning rules for the category inclusion
4. Refer to the sentence from which text was drawn and any wider background information
5. Acknowledge any limitations of the data to combat inappropriate generalisations

It was imperative to be able to imagine the emerging categories as questions so they could be part of the future interview schedule. Following Holsti' guidance, the intention was to construct categories that would be exhaustive and mutually exclusive. However, he accepted that even the most carefully designed study is likely to fall short of providing an exhaustive list (p99), and that mutual exclusiveness in constructing independent categories is also very hard to satisfy.

An independent reviewer was given random 50% of the incident report free text entries (a total of 625 reports). Although this seems a very large number, many texts were brief and it was decided that to gain a broad perspective on context, a 50% sample was required. The reviewer, a more experienced post-doctoral qualitative researcher who had published with the researcher [see Armitage & Hodgson 2004] read the sample over a period of approximately 3 months but was not privy to the researchers' categories. He was given the data with Holsti's documentary analysis framework, and the requisite error definitions to produce a written commentary on the findings with a list of possible categories.

4.7 Limitations of the data

Limitations of the data will be considered alongside the findings, however, alerted to the brevity of some of the reports through the pilot data extraction it was decided that two key aspects of Scott's work on institutional records (Scott 1990) could also be used to expand the dimensions of analysis. The first of these aspects is illustrated in what he sees as the raison d'etre of institutional documentation:

'all official records are produced in a particular administrative context involving everyday routines which are established to meet the requirements of the agency/organisation involved…..although an organisation is generally required to produce knowledge in a particular form, it may have to adapt these requirements to the needs of its efficient day to day operations'

(Scott 1990. p83)

Secondly, Scott has proposed that the information revealed in official documents such as incident reports can illuminate tensions between particular occupational groups in a given organisation, and might be indicative of two mutually exclusive perspectives – the clinical and administrative. In contrast to the clinical, the administrative perspective views the report as an actuarial record, or a tool with which to assess risk (Scott p.124).

4.8 Conclusion

This chapter has described the method for selecting, extracting, classifying and analysing a definitive sample of incident reports based on drug errors. Ethical approval was given on the condition that all data was anonymised and that no documents were removed from Trust property. The sampling size was modified following a pilot study based on the time taken to extract and record the details of 10 errors. Extraction was carried out using a specifically designed tool. Specific measures were applied to increase the validity and reliability of the procedure based on published definitions, and an established drug error reporting taxonomy. The quantitative analysis was implemented under the supervision of a statistician – who had also contributed to the design of the data extraction tool. 10% of the sample was subjected to a measure of inter-rater reliability, using the kappa statistic. A framework designed solely for documentary analysis was selected for the qualitative analysis. The qualitative analysis was also subjected to an independent review process, where a qualitative researcher read 50% of the free text entries.

CHAPTER 5: FINDINGS FROM STAGE 1

5.1 Introduction

Having described the method used for collection the incident report data (Stage 1); this chapter will describe the findings from the incident report analysis. Data were collected from the 1253 reports submitted across a five year period from the beginning of 1999 to the end of 2003. This yielded 991 drug error reports which were defined using the NCCMERP definition (see page 113). The 262 reports excluded from the sample were largely blood transfusion errors and other incidents which did not fit the NCCMERP criteria, e.g. adverse drug reactions. The 991 reports were subjected to a quantitative and qualitative analysis. The quantitative findings are presented before the qualitative findings. The data were collected using the data extraction tool previously described and the resultant data although sometimes lacking detail, were considerable in volume. Other aspects of the data were incomplete, and less relevant to the subsequent stages of the study. For these reasons and the limits placed on the size of the thesis, some data is not presented here: patient involvement [in the error], patient age, patient gender, whether relatives were informed, and the date and time of the report.

5.2 Stage 1: Quantitative findings

The rate of clinical incident reporting compared to patient accident reporting in the study trust demonstrated a sharp rise from the summer of 2000, which coincided with a change in the reporting system and a publicity drive from the risk management department to encourage clinical reporting. The continuing rise may have also been affected by the impact of catastrophic drug error in 2001 (see p.115). The data extraction tool was used to extract key drug error data from the incident reports. All definitive drug errors (those aligned with the NCCMERP definition) were extracted from a random 50% sample of all reported drug incidents

in the five year study period (n=1253) and are shown in Figure 5.1, the total number of definitive drug errors was 991. Adverse events resulted from 10 (1%) of the errors.

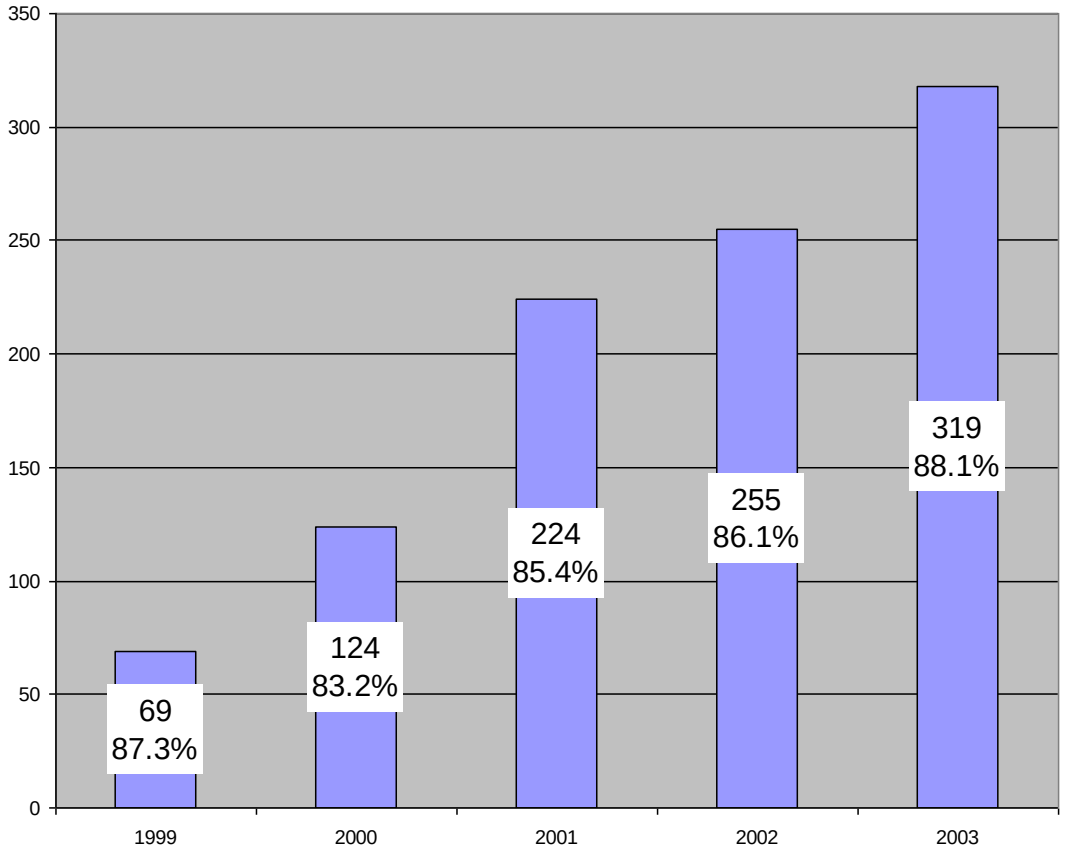


Figure 5.1: Frequency/percentage of definitive drug errors by year (n=991)

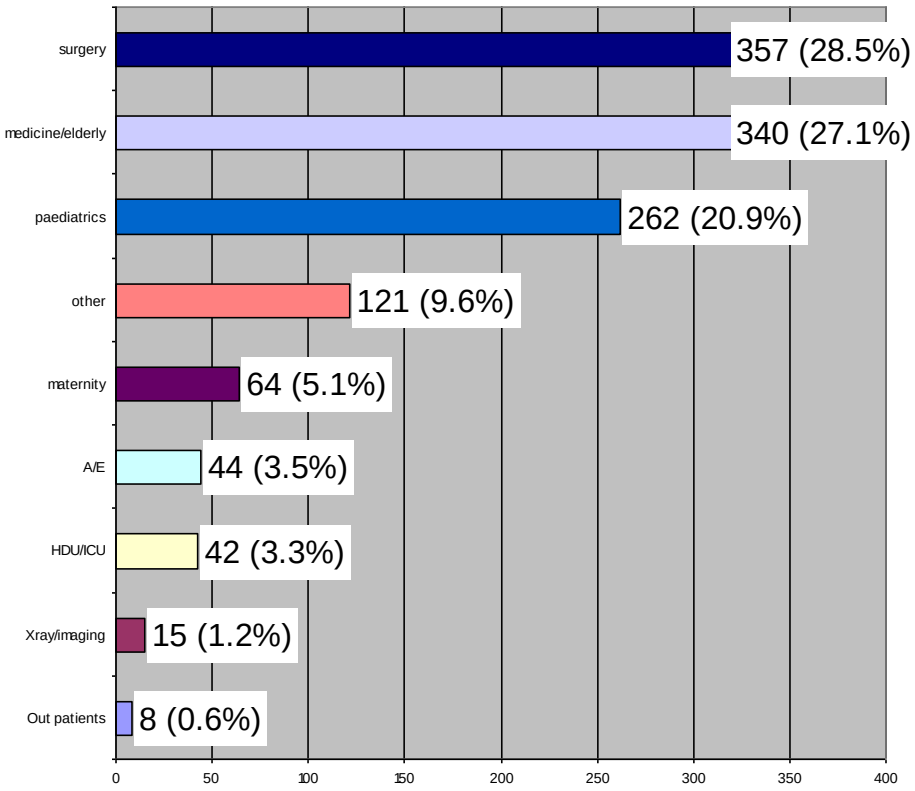


Figure 5.2: All submitted reports by clinical speciality (n=1253)

Figure 5.2 shows that the surgical department in the trust (including all theatre units) submitted most reports, followed by the medical and paediatric units. Mean rates of finished consultant episodes (FCEs) as a denominator for submitted reports can give a crude reporting rate, according to one measure of patient activity. Here it suggests a drug error is reported in 2.64% of paediatric FCEs, 0.88% of medical/elderly care FCEs, and 0.64% of surgical FCEs.

The NCCMERP stressed that their taxonomy is dynamic, that practitioners and risk personnel should expand it as they see fit and that both error 'types' and 'causes', can in any case, be multiple. Using the NCCMERP definition of a drug error and the accompanying framework, it was possible to identify error types in all of the definitive drug errors (Figure 5.3). The leading error type was dosing error 267 (26.9%) which when subdivided showed overdose to be the most common 136 (50.9%). However, 26.1% were classified as 'other'; either being less than 2.5% individually [e.g. wrong rate] or out with the taxonomy.

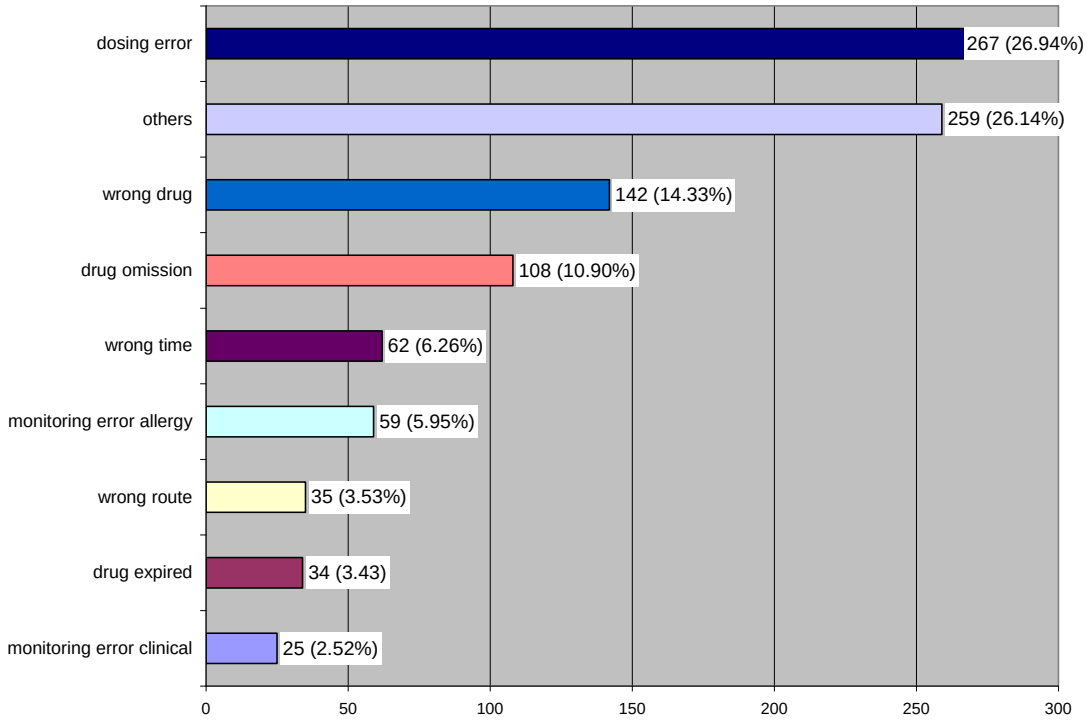


Figure 5.3: Frequency/percentage of definitive drug error types

In 27% of definitive drug errors, neither causes nor contributory factors could be identified from the incident report free text (Figure 5.4). Over the 5 year period however, there was an overall fall in the percentage of drug error reports with no identifiable factors, from a peak of 37.0% in 2000 to a mean of 25.4% in the subsequent 3 years. Examination of the error types: wrong drug, and monitoring error allergy (where a patient received or was to potentially receive a drug to which they were known to be allergic) showed no identifiable cause or factor(s) in 30.9% and 54.2% of cases respectively. Where however contributory factors were identifiable in the free text, the two leading factors were related to communication – whether this was written miscommunication, [e.g. a senior house officer writing a prescription illegibly], or a communication system breakdown. Whilst Figure 5.4 may give the impression that the various factors exist independently, the subsequent content analysis, where content was adequate, suggested not. For example:

Circumstances: discussed the incident with doctor, I asked to administer salbutamol 5 mgs via nebuliser, following which the patient developed a tremor and

fast pulse. Prescribed medication then found to be inhaler and not nebuliser. I feel following this incident the demands placed upon all staff on this shift left us open to potential errors in practice' Cause: staff levels and work load. Action: [nil comment] 417/00

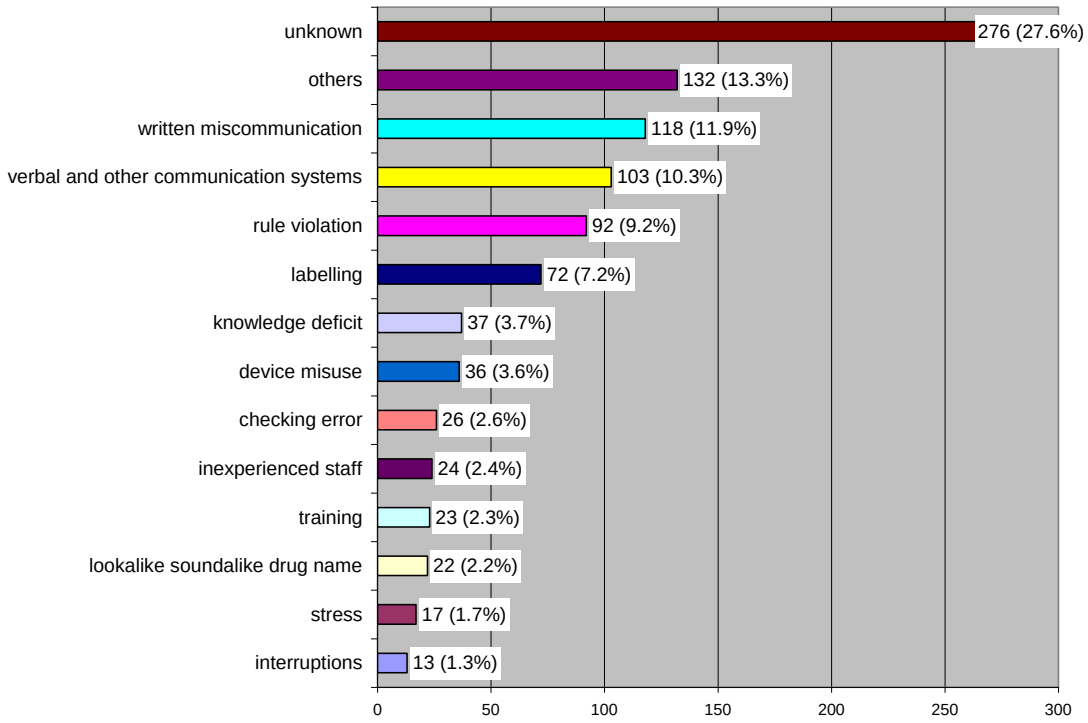


Figure 5.4: Frequency of contributory factors in definitive errors (%)

Inter-rater reliabilities for key judgements were calculated on a random sample of 95 of the incident reports previously reviewed using the Kappa (κ) statistic. Agreement on what was/was not a definitive drug error was only fair (κ = 0.39), on what was/was not a near miss was good (κ = 0.71), and on error type was very good (κ = 0.86). However, when raters are classifying both common and rare event types, the latter (or unusual drug error types) tend to produce high expected agreement, thereby rendering Kappa less valid, as discussed elsewhere by Subbe et al (2007).

There were 25 options for contributory factors but Kappa was not used here as there were a considerable number of errors where multiple factors were identified. Alternatively, contingency tables were constructed to assess agreement. There were notable differences in the attribution of the factors 'performance deficit' and

'unknown' (see Tables 5.1 & 5.2). First, the author did not attribute the term 'performance deficit' based on the available data, whereas the independent reviewers attributed the factor in 34 error reports. The author's caution about attributing causation from these data was also evident from his classifying far more error reports as having unknown contributory factors than the independent reviewers. In fact 16 of the reported errors originally classified by the author as having 'unknown' factors were then classified by the independent reviewers as 'performance deficits'.

Table 5.1: Attribution of the factor 'performance deficit'

Performance deficit	**No (Ind. Rev)**	**Yes (Ind. Rev)**	**Total**
No (GA)	61	34	95
Yes (GA)	0	0	0
Total	61	34	95

Table 5.2: Attribution of the factor 'unknown'

Unknown factor	**No (Ind. Rev)**	**Yes (Ind. Rev)**	**Total**
No (GA)	69	2	71
Yes (GA)	22	2	24
Total	91	4	95

Nurses were the most prolific reporters of definitive drug errors (80.2%). Doctors formed 6.97% of reporters and of these 56.5% were senior registrars or consultants. Pharmacists appeared to form only 5%, but within this trust, the majority of pharmacists use a regional reporting system, sometimes additional to the trust system but also instead of the trust system. Expressing the figures however as a percentage of their respective professional populations, demonstrated that 54.1% of the nursing workforce reported, 12.9% of doctors, and 151% of pharmacists (each pharmacist reported at least one error). The population of protagonists in a definitive drug error, mindful of the above percentages of reporters, was dominated by nurses but by a much smaller margin (40.8%); also

the number of protagonists who were doctors was greater (12.7%) clearly demonstrating that reporters can be vicarious or 'second hand'. In 37 reports, nurses were subject to disciplinary action and or counseling following an error, compared to 5 pharmacy staff, and 1 doctor.

5.3 Stage 1: Qualitative findings

5.3.1 Overview

Whilst the report format in 1999 and the first quarter of 2000 differed from the subsequent and predominant format, almost all reports in the sample had three text boxes (Circumstances, causation, action taken). Circumstances were able to be documented in all the reports. Although a text box titled 'Other' at the end of a list of predefined causes in the earlier format had very little space for causation, reporters were still given a prompt with the option of 'giving further details' on causation in a box titled 'circumstances'. Action taken was documented in a subsequent box. A small number of reports in 1999, stemming from 1995, did not have a box dedicated to action taken (n=8). However, some staff still commented on action taken through the box titled 'circumstances'.

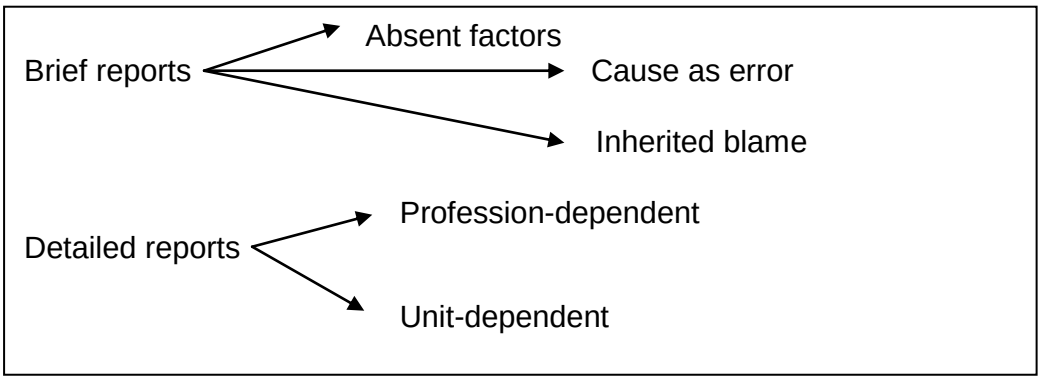
Despite a text box having then been made available for 'causes' in all reports within the study period, causation or contributory factors were not always identifiable from the report text. Whilst this has already been described and presented above as a quantitative finding, (contributory factors absent in 276 / 27.6% of reports), this initially emerged from a qualitative analysis of the free text. To contextualise the qualitative findings, a review of the number of reports per year without an identifiable contributory factor, as a percentage of the reports sampled per year is shown in table 5.3. Although from 2001, there was clearly a fall in the number of reports where factors could not be identified, the downward trend did not continue.

Table 5.3: Number of reports received without cause or contributory factor

Year	Number of reports rec'd without identifiable cause or contributory factor (n=276)	Percentage of sample for that year
1999	24	34%
2000	46	37%
2001	56	25%
2002	69	27%
2003	81	25%

Having followed the application of Holsti's framework for the content analysis of documents, and influenced by Scott's perspective on institutional documents, two primary categories of meaning emerged: 'The brief report', and 'The detailed report'. Under the primary category of brief reports were three sub categories: 'absent factors', 'cause as error', and 'inherited blame'. Under the other primary category of detailed reports were two sub categories of 'profession-dependent' and 'unit-dependent'. The categories are displayed in Figure 5.4 below.

Figure 5.4: Primary categories from qualitative analysis



In line with Holsti's guidance (Holsti 1969, p50), the coded categories are described below. A definitive statement is offered for each category, followed by the reason they were selected, and an illustrative quote (with background information if necessary). Differences in style, documented process, and action taken are described - any related intra-professional, inter-professional or departmental trends are also commented upon. The co-rater's perspective is then given, and finally how the different categories compared and any limitations in the data. To consider

the nature of any change over time, report extracts have been drawn from across the 5 year range.

5.3.2 The brief reports

A yearly total of reports classified as 'brief' is given in table 5.5. The brief report was one where the reporter has access to relevant information but didn't provide sufficient evidence of process and outcome to demonstrate an adequate understanding of the error to be entered into a risk database for organisational learning. Brief reports tended to exhibit one or more of three characteristics, which became the sub-categories.

Table 5.5: Total of brief reports per year

Year of report	Number of inappropriately brief reports (n=345)	Percentage of total reports received in that year (Mean 33.8%)
1999	20	28.9%
2000	40	32.2%
2001	82	36.6%
2002	60	26.6%
2003	143	44.8%

Presumably, brief reports would have also emanated from a reporter simply finding an error which may have arisen from factors with which they were unfamiliar, [e.g. a nurse may find a dispensing error but has no idea of causation]. Consequently, those reports where detail would be have been impossible to obtain before submission, were excluded from the count of brief reports.

5.3.2.1 Absent factors (276 in this category)

Definition: where there was no identifiable cause(s) or contributory factor(s) in the completed report. These reports were selected as they seemed to lack a logical linkage between the various stages of the report [e.g. cause and action taken] providing little or no opportunity for individual or organisational learning. Some reports had no actual text; alternatively, an error type or non-causal statement

about the patient's condition was offered, [e.g. 'drug overdose' or 'patient allergy']. It can also be seen from the extract below that 'causation' was recorded by the reporter's manager rather than the reporter – the prescribing element of the error was not made explicit. The term '*protagonist*' is the practitioner closest to the error although this may be at the time of reporting and not always at the time of the error occurring:

Circumstances [protagonist]: 'about to give IV tazocin as prescribed when noticed that patient was allergic to penicillin. This was second dose, so one already given, await review. Cause [superior]: patient allergy. Action [superior]: copy to all involved and discussion with nurse concerned' (80126/03)

5.3.2.2 Cause as error (48 reports in this category)

Definition: where the term 'error' summarised causation. In these reports, characterised by their brevity, the term 'drug error' or 'human error' seemed to be used as a blanket statement to identify causation. They were selected because the text appeared to demonstrate a lack of understanding about the concept of human error. These short terms were found in the boxes for 'circumstances', 'underlying cause', or 'action taken' but were usually in 'underlying cause':

Circumstances [protagonist]: '…patient prescribed cefotaxime 1g and metronidazole 500 mgs, [and] I misread the prescription and administered cefuroxime 750mgs and metronidazole instead. I realised this morning when going to administer the next dose. Cause [superior]: drug error
Action [superior]: nurse asked to be more vigilant, and follow Trust policy' 45658/00

Circumstances [protagonist]: whilst giving patient's night time medications, I noticed that her evening dose of insulin had not been signed for, I felt it inappropriate to ask the patient if it had been given (had been confused), I decided as it was late, not to ring the nurse who had administered the drugs earlier. Blood sugar was 12.8, and I continued to monitor blood sugar levels overnight. I informed the nurse in charge

next morning and realised I should have alerted the doctor. Cause [superior]: human error. Action [superior]: dealt with through disciplinary procedure. 65367/03

The practitioner above (report 65367) was brutally honest about her actions which are clearly concerning. While a cause was not explicit, the action taken was very clear.

5.3.2.3 Inherited blame (34 reports in this category)

Definition: where the content of the report was centred on an individual(s), and their faulty actions. Attention to causation was either absent or cursory. There was however, explicit evidence of assigning full culpability in the action taken, appearing to have been inherited by the individual, simply by being involved or having submitted a report.

These reports were inclined to identify and sometimes discuss the individual(s) involved rather than any systems involvement, and how they were subsequently seen by their superior. They were selected as they provided an insight into the culture of medical error and reporting. In some of the reports identified, the error was described (and perhaps assumed) by the superior, solely as a policy violation (rule violation):

Circumstances [protagonist]:'patient given 10mgs of maxalon by mistake, explained to patient. Cause [superior]: nil. Action [superior]: Seen by nurse manager, failure to comply with drugs policy. Will take greater precautions' (43685/00)

Circumstances [protagonist]: 'I gave by mistake, about 10 mgs (0.5mls) of iron sacchara to the patient – but the prescription of iron saccharate had stopped on 20.8.02. In the syringe was 2.5mls (50mgs) of iron saccharate. I had the prescription in front of me and as soon as I noticed the error, I stopped at once. Cause [superior]: the nurse realised what she had done and stopped. Action [superior]: nurse involved has had to demonstrate to charge nurse, the appropriate

procedure for the administration of medicines.' 71424/02

In report 80069/03, a monitoring error was described by a third party [e.g. ward sister] as a violation. However, under 'cause', important systems issues were mentioned which suggests this may not have been a routine violation, yet the term 'violation' seems to have been employed in a generic sense:

'insulin sliding scale not checked for three hours – should be hourly – violation protocol. Two other patients on the same ward – same story. Cause: staffing levels poor for this ward, situation of error discussed, staff sickness also a problem' (80069/03)

Reason has actually proposed how practitioners at the front line of health care are more likely to be the inheritors rather than the instigators of medical errors (Reason, 1997). Nevertheless, a range of text here suggests there may be a different view amongst those involved in the reporting process, which may result in blame. Whether the practitioners involved had engaged in unsafe acts, or had been in contact with systems/organisational failures, *they* became the centre of attention. A specific report and its attachments illustrated this:

Circumstances [protagonist]: 'Whilst caring for the patient her respiratory rate dropped to 8bpm, the epidural was reduced over two hours and eventually stopped at midnight, patient was also hypotensive, over the course of the night she was seen and examined by medical staff and treated, she eventually improved. At 0730 whilst checking the controlled drugs, to order for the weekend, I noticed that 3 PCA syringes were missing, at 0735 I found a PCA syringe attached to the above patient's epidural giving set.' (45302/00)

Attached statements from the staff nurses concerned described their sadness at the error and that they *'had not checked the syringe (to be attached) properly'*. They also stated that *'the ward was very busy, and that there were agency nurses*

to be supervised.' However, the manager stated under 'cause' that the administering nurse had *'failed to recognise the drug against the prescription. Although medical and nursing staff recognised the patient's deterioration, they failed to connect this to the wrong drug being administered'* Under 'action taken' it was documented that *'staff concerned will be seen under the disciplinary procedure to ensure they follow the procedure in future'*

Whilst the statements gave some indication of the contributory factors, the report did not. Indeed the lack of analysis in the overall reporting process may have facilitated blame. Nursing staff also appeared to be more likely to undergo blame than doctors. Report 51787/01 provided yet another example of inappropriate brevity (see the cause) but was also an example of a nurse-focussed report even though it was at root, a prescription error:

Circumstances [protagonist]: 'Checked ranitidine with TNR nurse. Gave 35mcgs instead of 3.5mcgs. The dot between the 3 and 5 was not visible. Checked the dose with another nurse and realised my mistake. I informed mum what had happened and that we were nursing the baby on a cardiac monitor for 24 hours. Cause [superior]: drug error. Action [superior]: 'staff reminded to check dose when decimal point not visible' 51787/01

The 'action taken' ignored the prescribing element of the error. Another very brief report likewise summed up the dilemma for nursing staff: '*incorrect prescription by the doctor but wasn't picked up by the nursing staff*' (59570/01).

5.3.3 The detailed report (275 in this category)

Definition: where the circumstances of the error were at least adequately described, there was explicit consideration of contributory factors, and this was logically linked to action taken. These data would be beneficial information for a risk database, with possible evidence of individual and or organisational learning. These reports were selected because they demonstrated that reporters could provide relevant

data. Methodologically, it was also important to be counter-intuitive (Silverman 2000) and balance the inclination to identify problematic reports.

The defining characteristics of these reports are exampled in the following extracts. The first only highlights one factor yet the circumstances are adequately described by the nursing staff concerned and there is demonstrable logic between the three stages of the report as well as a tangible outcome:

Circumstances [protagonist]: 'on checking prescription chart, I found that she had been prescribed tranzenic acid but this should not have occurred, should have been for different patient. Medical staff informed. Cause [superior]: more than one patient with the same surname on the ward. Action [superior]: memo to ward staff to check patient ID numbers' 83681/03

The second example is from a very different clinical context (intensive care unit), and submitted by a doctor:

Circumstances [protagonist]: 'known iodine allergy. Verbal order from surgeon for NG contrast, nursing staff checked the bottle – no mention of iodine on bottle. NG contrast given. No reaction noted, when allergy noted, remaining contrast aspirated. Cause: contrast bottle does not state all ingredients. Action: clearer labelling, specific advice from radiology as to whether safe to give to iodine allergy patient. Also used for those with skin allergy to iodine – as told by radiology registrar. Should contrast be prescribed by radiologist?' (70487/02)

Some of these detailed reports although concise can highlight faulty systems (or ways of working) that are significant factors in causation:

Circumstances [protagonist]:'iv aminophylline 120mls given in error rather than 90mls as bolus over half an hour. Prescribed as 90mg bolus over 20 minutes then to revert to 18 mgs / 18 mls per hour. Limits omitted – to be inputted prior to commencement. Therefore larger dose infused. Drs. informed and advised to

continue running through at 18 mls per hour (1ml/kg/hr). Cause [superior]: Occurred when two nurses involved, one started the infusion, and the other finished (as opposed to skill deficit). Action [superior]: staff advice/counselling'.

Finally, the detail around the process of double checking seemed to be a particularly concerning factor where typically two nurses would check a drug, having followed some process, but there would still be an error:

'patient given 5mls of oromorph instead of 5mgs. On checking the drug, both nurses checked and misread the dosage. When realised patient had already had the drug, doctor informed immediately' (7974903)

Relative to the number of reports submitted by profession, detailed reports were more likely to be from medicine and pharmacy than nursing, they were also more likely to emanate from a particular clinical unit. Consequently, the following two sub- categories emerged.

5.3.3.1 Profession-dependent

Definition: where differences in the content of reports fell into specific styles according to the reporter's and manager's professional status [i.e. doctor, nurse or pharmacist]. These reports were selected because they may have been indicative of profession-based subcultures within a setting that might have influenced both reporting processes and outcomes. As mentioned earlier, it was apparent that nurses were more likely to be blamed than either doctors or pharmacists. Perhaps as a consequence, their response to an error was often unrealistic, and consequently self-deprecating:

Circumstances [protagonist]: *'Staff nurse left a ventolin syringe on side table in ward for a patient whilst waiting for air cylinder from another patient. But patient then drank it'* [Accompanying statement] *'I will under no circumstances leave a prescribed medicine on a patient's bedside table again unattended. I discussed*

with ward pharmacist and she said it was unlikely to be a problem' (30874/99)

When nurses were involved in a reported error they seemed to become part of a management process - where their superiors existed in a management rather than clinical role – in contrast to their medical colleagues. There was also a contrast in the reports completed by doctors compared to nurses. They generally held more detail but also suggested a more learning-centred process in the action taken:

Circumstances [protagonist]: 'Patient prescribed insulin on insulin chart (attached), 81 units prescribed and nearly given – should have been 8.1 units. Cause [superior]: unknown. Action [superior]: all medics shown correct way to prescribe insulin' (25041/99)

Action taken [superior]: 'It appears the dilution of the syringe contents was incorrect, noradrenaline is presented in 4ml ampoules at a concentration of 1mg per ml, I imagine whoever prepared the syringe mistakenly believed that the ampoule contained 1mg in total and therefore diluted 4 ampoules (16mls) with 34mls of saline, I have spoke to senior nurses and doctors in A/E about this and we will anonymise the case for discussion in our trust' (41350/00)

Doctors were also less emotive and tended to be self-advocating, noting how the systems surrounding them had a clear bearing on the protagonist. Pace of work was not uncommonly seen as a key factor in doctor's reports, perhaps suggesting a stream of confidence in their own ability which had been disrupted by environmental pressures:

Circumstances [protagonist]: '*patient seen by surgeon on ward round and told to take 15mls orally and recommence IV. Due to all doctors working for the surgeon concerned being unavailable, the patient was without IV fluids until 4 pm when a doctor from another team inserted a venflon. Surgeon made aware of the situation. Cause [superior]: 'no medical officer for the team available, they were busy with*

their own duties in clinic and hard pressed at that.' (45307/00)

That there were more reports from senior medical staff than junior may have accounted for the much broader (systems) perspective taken. As above, they did not employ the language of blame (disciplinary action, counselling, formal warning, etc) sometimes seen in action taken, this was particularly evident here:

'Circumstances [protagonist]: in resus dealing with another patient when I was called by pharmacy to inform me that I had prescribed magnapen for the above patient who is allergic to penicillin, agreed to change to erythromycin. Cause [senior]: had been called to resus while dealing with above patient, wrote prescription and was going back to check allergy status with mum but forgot. Action taken [senior]: I discussed the incident with Dr. H who at the time had been called to the resuscitation room to see a critically unwell patient and was then asked to complete a prescription form. Dr. aware that magnapen is contraindicated in penicillin allergy and the cause of this incident would appear to be a combination of a new doctor who is not yet completely familiar with the medical records present in the AE department, having had her consultation with the patient interrupted to see a critically ill patient. This resulted in a lack of continuity resulting in the error. I have discussed the detail of the error with the doctor and I am sure this will not occur in the future.' (75137/02)

Of course, drawing any firm stylistic conclusions from such a small number of doctor-initiated forms is difficult, nevertheless just one medically led report in the sample suggested a blame approach without any acknowledgement of cause (80760/03).

Pharmacist-initiated forms were even fewer largely due to their use of a parallel reporting system – specific to drug errors. Pharmacist-authored reports, although poorly represented in the group were somewhat of a hybrid group displaying some of the characteristics of medical and nursing reports. However, pharmacists and

their departmental colleagues, the pharmacy technicians, appeared more inclined than nurses to acknowledge systems factors, and especially pace of work as a contributor to error:

Circumstances [nurse on the ward]: 'a tube of nystatin cream was ordered as a take home medicine and a tube sent, but not the correct tube – it was nystaform. Cause [senior pharmacist]: Pharmacy was experiencing an 'exceptionally high workload' on this Saturday afternoon. The nystaform simply contains chlorhexidine as well. It is unlikely the different treatment would cause harm. We are facing serious difficulties maintaining the week end pharmacy service and our staff are doing their best to cope with the level of work – and feel it would be unhelpful to pursue this incident' (60787/01)

Importantly, the inter-professional differences in the content and style of reporting described above were sometimes less marked when the staff came from a particular unit.

5.3.3.2 Unit-dependent

Definition: where differences in the content of reports fell into specific styles according to the reporter's clinical unit or ward [e.g. oncology, accident and emergency]. These reports were selected as they showed that in one particular unit, a range of staff, could proffer detailed reports that took a circumspect but analytic view of drug errors, without recourse to unnecessary blame. The most consistent example of such a unit was the neonatal unit, which also submitted more reports over the five year period than any other individual clinical unit or ward:

Circumstances [protagonist]: 'noted at handover that infant's dexamethasone had not been signed for. Nurse involved in infant's care could not be contacted – doctor suggested not to give drug. Also noted the drug was not prescribed on medication sheet, only on dexamathasone sheet. Action [superior]: 'problem due to use of wrong prescription sheet – consultant neonatologist to see medical staff about the

prescription sheet process' (62034/03)

Circumstances [protagonist]: 'due to work load pressure, trimethoprim missed at 2200 hours, mistake was noticed at 2am when more time could be spent with the baby. Cause [superior]: nursery nurse had 5 babies to care for in one room and forgot to ask the only registered nurse in the room to get the medication until late on the shift. Action [superior]: ongoing work with nursery nurses to look at training issues, awaiting registration of Filipino nurses to ease workload' (70746/03)

Reports such as those above probably provide some evidence of why reporting rates and the nature of reporting may differ by unit. The action taken explicitly acknowledges the role of systems in error occurrence. Report 85560/03 further emphasised this, and in another report, clear support was demonstrated in 'action taken' for the staff that had submitted the report (44417/00):

Circumstances [protagonist]: 'working in nursery one and overseeing 1 unstable ICU baby, 3 high dependency babies, and 1 Philipino nurse. One baby due flucloxacillin 8 hourly, no warning from Philipino nurse about due drugs, this nurse thought drug was prescribed BD. I gave the drug five hours late. Cause [superior]: staff shortage, supervision responsibilities, and high dependency babies led to confusion over timing of drugs. Action [superior]: ongoing training and supervision of overseas nurses' (85560/03)

Action [superior]: 'I feel following this incident the demands placed upon all staff on this shift left us open to potential errors in practice' (44417/00)

5.3.4 Independent review of qualitative data

As explained in Chapter 5, an independent reviewer was given a random 50% of the incident report free text entries including those incidents that were not ultimately classified as drug errors (a total of 625 reports). His analysis included a general commentary on the data and some suggested categories. A shared discussion

suggested there was a relationship between his categories and those of the author. Nevertheless, the language he used to describe his categories was noticeably different – possibly due to his ethnographic background. Furthermore he raised two questions which he believed to be potentially useful triggers for alternative categories. Figure 5.6 shows both shared categories and the two questions. A brief synthesis of the co-rater's comments with those of the researcher is discussed further in Chapter 11.

Figure 5.6: Independent reviewer's comments on the qualitative data

Common categories between researcher and independent reviewer [Stated in reviewer's terminology]

Unknown circumstances [regarding the error]
Lack of analysis [of causation]
Poor patterns of communication [as contributory factor]
Professional boundaries [influence response to the error]
Correctional activities [are prescribed for individuals who have been involved]

Co-rater's questions?

Who is the expert in the incident or error?
Whose reality [is being portrayed in the reports]?

5.3.5 Summary of the qualitative categories and limitations

Although the primary categories were mutually exclusive, the sub-categories represented recurrent instances in the text which were inter-related. Some reports illustrated more than one sub-category, such as the cause was solely described as 'human error', and in action taken there was evidence of inherited blame. The subcategories under 'The detailed reports' were again related. There were instances of unit-based differences in the content and style of reporting that also appeared to be profession-dependent, although as stated earlier this was sometimes less marked when the staff came from a particular unit.

The process of analysis and the resultant categories have provided a range of topics that require further exploration. Although some inferences have been made on the *effects* of these reports as communications, obtained through reference to 'action taken'; a specific limitation is the lack of data on the antecedents of these

reports. It can however be hypothesised that the definitive drug error reports were submitted as a result of staff following hospital policy concerning what they perceive to be worth reporting, in the interests of patients and effective risk management. This is, however, an assumption and together with several other assumptions supports the need to interview a sample of reporters as was planned for Stage 2 of the study.

5.4 Conclusion and construction of the interview schedule

This chapter has presented a series of findings from an analysis of the quantitative variables, and of the free text, from a sample of 991 definitive drug error reports. In combination, they have demonstrated that the reporting process has a number of notable characteristics. While error types can be extrapolated, contributory factors are not always identifiable. Inter-rater reliability measures for what is, or is not a drug error, and the attribution of contributory factors from free text, imply that the judgement of these variables lacks consistency. There are differences in reporting rates by speciality and by profession. The nature of the free text also differed by profession, and by clinical unit. Approximately one third of reports provided insufficient data for effective risk management, and *learning*. There was a lack of logic in addressing causation, and a lack of coherence in linking circumstances to causation and action taken. Nevertheless, the quantitative and content analysis of the error reports from stage one, together with the independent reviewer's comments, provided the format for a semi-structured interview schedule, as originally planned. Table 5.5 shows those aspects of the study aim that required further exploration, based on gaps and uncertainties in the preceding analysis (left column), and the corresponding focus for the qualitative interview schedule (right column).

Table 5.5

Stage 1 findings that require further exploration and their corresponding focus in the interview schedule

Notes: some of the findings that require further exploration share the same corresponding focus in the schedule

Possible leading questions are in bold text

Stage 1 Findings that require further examination	**Corresponding focus for interview schedule: possible questions**
The steady rise in reporting drug errors (and near misses)	**Tell me about reporting incidents** Tell me about reporting errors that don't impact on the patient or 'near misses'
Variation in reporting rates by clinical location	Are certain errors/types of errors more commonplace in your unit?
The predominant contributory factors	**Can you describe for me the most recent drug error you can remember?** I would now like to know if there are any particular contributory factors that generally increase the likelihood of drug errors being made? Can you give examples and explain why these factors are apparent? Do you think sometimes there are several factors involved at the same time?
Absence of contributory factors in reporting (nature of the reporting process and who is involved in attributing causation)	Who do you think is best placed to document the causes /contributory factors in an error? Why?
Drug errors being perceived as rule violations	Do you think some drug errors break policies or protocols? Do policies and protocols help to promote medication safety/reduce errors?
Drug error reporting rates and styles which differ according to the profession of the reporter	Do you think drug error reporting is perceived differently by different professional groups/members of the trust?

Stage 1 Findings that require further examination	**Corresponding focus for interview schedule: possible questions**
Double checking (known to be a defence) seemed to be a contributory factor	Are you familiar with the idea of double checking? How can double- checking be helpful in reducing drug errors? Can you tell me about other activities / key individuals that might 'weed out' or reduce the risk of errors?
Drug errors being seen as caused by blameworthy individuals	**Tell me about reporting here in the trust.** Would some factors be more sensitive than others to report? In your unit/experience, might some staff make the same sort of errors over and over again?
How the reporting process might be improved	**Are there strengths and weaknesses in the reporting process, what are these and why?** Are the circumstances that you or your colleagues document on an IR a clear record of the circumstances of a drug error? Are you able to write what you want or need to write? What are the priorities in your opinion when completing the 'action taken' section? From what you know about the reporting system here, what sort of improvements could be made? Would you envisage a separate reporting process for drug errors compared to other errors?

CHAPTER 6: METHOD FOR THE QUALITATIVE INTERVIEWS (STAGE 2)

6.1 Introduction

Having presented the findings from the documentary analysis, this chapter will describe the data collection and analysis process employed for the ensuing qualitative interviews. All data were collected from 40 individual interviews between May and September of 2005, and the subsequent analysis was in three phases. On the basis of the previously reviewed literature, it was decided to construct a multi-disciplinary sample consisting of the three professional groups who were instrumental in the delivery of drugs to patients – pharmacists/pharmacy technicians, doctors and nurses. However, the small number of pharmacy staff compared to the other two groups, together with advice from the Director of Pharmacy, suggested that their recruitment would be more difficult and consequently the sampling frame was adjusted to include less pharmacists. It was essential to begin discussions concerning the design of the enhanced scheme with the trust's senior officers and those responsible for risk management as soon as possible. Consequently, those aspects of the data that could directly and practically inform an enhanced incident reporting process were extracted and analysed before any other data – guided by the 'Framework' model (Ritchie and Spencer 1994, Ritchie et al 2003b). Secondly, there followed a broader, deeper analysis of the entire data to develop a view of how participants' beliefs concerning drug error generated their orientation to the problem, their description of contributory factors, and whether this was profession-specific. The latter analysis was also designed to construct a coherent picture of how reporting was perceived as means of attending to drug errors. The most prevalent concepts were ultimately organised into coded categories. Thirdly, a sample of transcripts was given to

another doctoral researcher for co-rating which confirmed the final refinement of categories and consequent theorising. This chapter is divided into the following discrete sections: sampling; recruitment and ethical considerations; materials and measures; procedure; and analysis.

6.2 Sampling

The study objectives demanded that the sample had specific characteristics. A purposive, volunteer sample was planned so as to recruit practitioners who through their role and experiences could potentially provide meaningful data (Robson 2002, Ritchie et al 2003a). These characteristics translated into just 2 criteria:

1. the participant must be a qualified doctor, nurse, or pharmacist
2. the participant must have had experience of drug errors and their reporting

Furthermore, the inclusion of three professional groups potentially provided a perspective from all those instrumentally involved in the provision of drugs to patients as also recommended by Pape (2001), but at different stages of the process, and as in Tamuz et al's sampling frame, working at different levels of the organisation's clinical hierarchy (Tamuz et al 2004).

While there is no ideal sample number for qualitative studies such as this (Huberman & Miles 2002), those using qualitative interviews that require comparison between groups within the sample require at least 40 participants (Gubrium and Holstein, 2002). However, Ritchie et al (2003a) also add that samples of less than 50 will reduce difficulties with data management.

Appendix item 10 shows the sample of participants listing the order in which they were interviewed, their profession, clinical base and gender. It included 15 doctors of various grades and from a range of clinical backgrounds. The 15 nurses similarly came from a range of clinical grades and backgrounds. The seven pharmacists were based in the trust pharmacy department but each had individual

responsibilities for a clinical area and sustained contact with the staff therein, one of the pharmacists also held management responsibilities. In addition, three pharmacy technicians were recruited on the recommendation of the Director of Pharmacy who explained that technicians were instrumental in the dispensing process, their experience of errors was considerable, and they used the hospital wide reporting scheme. Access to staffing numbers for the three professional groups showed 1466 nurses, 533 doctors, and 33 pharmacists. With a much smaller pharmacy group relative to the other groups, it was thought that recruitment could be difficult, which was further exacerbated by staffing levels at the beginning of the data collection period being reduced by 15%. Consequently, as the prevalence of a subgroup population is a key factor in generating a sampling frame (Ritchie et al 2003a), the projected requirement for pharmacy representatives was lowered from 15 to 10. However, this number would have been increased if analysis did not allow conclusive data saturation (Morse 1995).

All staff had been qualified at least 3 years. The nursing and medical staff grades were particularly wide ranging, although the pharmacists and pharmacy technicians were predominantly senior, and all had been qualified at least 5 years. To protect the confidentiality of certain staff, it has been necessary to avoid detail that would potentially compromise their anonymity, especially where there was only one person carrying the specific title within a named department. There were 13 males and 27 females.

Mason (1996 p91-92) describes three potential relationships between the sample selected and the greater population: a representative relationship, a detailed relationship, and finally a relevant relationship. The latter was evident here, where the sample provided a relevant range of individuals that were related to, without being directly representative of, the greater trust population.

6.3 Access, Recruitment & Ethical Considerations

Recruitment was a challenge. A total of 47 potential participants volunteered. Appendix item 11 shows the recruitment flyer which was circulated through departmental heads, as well as being advertised in the trust newsletter and the trust intranet. Responses to the advertisements were minimal, but departmental heads through their team meetings, simultaneously provided a much greater supply of potential recruits, and were able to immediately give out information sheets to all present. Participants also came from attendance at departmental meetings and multi-professional clinical governance groups (departmental visits), having originally been invited to give presentations on the study. Additionally, when the author was in departments arranging to meet participants, other staff members would sometimes ask about the study and this served as yet another form of recruitment. Recruitment sources are shown below in table 6.1.

Table 6.1: Interview participant recruitment sources by totals

Recruitment Source	Total
Departmental Head	17
Departmental Visit	8
Trust Meeting (Drugs & Therapeutics)	5
Intranet	4
Attendance at Clinical Governance meeting	3
Snowball	2
Newsletter	1
Grand Total	40

All staff who expressed an interest in the study were given access to an information sheet (inclusive of the consent form) with the requisite details to contact the author via email or telephone if they wished to take part (Appendix item 12). Information was given about the design and purpose of the study, making clear the potential benefits. The information sheet also briefly described the interview process, offering an example question to reassure participants about the level of difficulty or comprehensibility:

'Do you believe drug errors are more likely to occur in certain circumstances, if yes, can you describe those circumstances to me?'

It was recognised that there was a risk of psychological harm posed by participating and this informed both the design of the information sheet and the style of interpersonal approach. The information sheet text was written in the first and second person to personalise the information. The principle condition of ethical approval was that all participants must receive a full guarantee of confidentiality and anonymity whatever they disclosed during the interview.

The Local Research Ethics Committee (LREC) decided on this approach so the author could establish an in depth and unfettered understanding of participants' experiences of drug errors and reporting. It was proposed by the LREC that if participants were given this guarantee, this would also relieve the author from considering what may or may not have to be disclosed in the public interest. This reflected the approach employed by Leape et al (1995), in collecting interview data for their systems analysis of adverse drug events. To protect the participant's autonomy, the decision to disclose any interview content to a third party rested solely with the participant.

The participants would be assured that there would only be one set of interview transcripts and these would be stored in a locked drawer; the electronic copies would be stored in a single, password-protected personal computer. The anonymisation process would include the complete removal of names from any research reports published in peer-reviewed journals or conferences papers. This meant each participant was given an identification number, and their corresponding names and clinical locations kept in a log book separate to the data transcripts. (A record which was then used to return the transcripts and summary reports to those who had requested them).

The commitment to confidentiality was bolstered by the author's declaration that he

had no affiliation to the trust, and while funded by the Department of Health, they held no ownership of the data. Ethnical approval was obtained on 23rd February 2005, see Appendix item 13.

6.4 Measures/Materials

The interviews were grounded in a qualitative methodology. One to One in-depth interviews were preferred to group interviews and focus groups. Such group approaches would demand the participants spoke in the presence of others about their (or their colleagues') involvement in errors, the reporting process and the organisational culture; something the author believed to be an unnecessarily arduous task for the participants mindful that the literature shows fear and other negative emotions to be key barriers to error reporting (p. 57-64). This stance was also, understandably, supported by the Ethics Committee. Although a focus group could provide additional insights into how the various participants were influenced and influenced each other (Finch & Lewis 2003), this study's objectives demand depth of individual detail, and practically – the most time-efficient means of recruiting the practitioners – focus groups are often time consuming to organise (Wilkinson 2004). An interpretative approach was taken, exploring how health professionals give meaning to drug errors and their reporting, promoting an holistic perspective which by definition, recognises the complexity of human behaviour (Denzin & Lincoln 2004). Consequently, the interview schedule (Appendix item 14) was not used as an absolute prescription of items to be covered but to facilitate a constructive dialogue (Arthur and Nazroo 2003). It was designed to provide sufficient structure to ensure both parties remained focused to the research objectives, but did not limit the potential for unanticipated but useful subject areas to be introduced by the interviewee (Legard et al 2003). However, the latter part of the schedule did necessitate a more dichotomous approach in order to obtain operational data on the structure of the existing reporting form and supporting process.

The use of closed questions within a qualitative approach was discussed with William O'Connor (O'Connor, in conversation 28.3.06); co-author in the most recent publication on 'Framework' (Ritchie et al 2003b p219-262). O'Conner suggested that questions are not important in their structure – they *should* be different in respect of what the questions wish to achieve as the researcher is required to explore different aspects of the topic, adding that the whole [of the data] should still be greater than the sum of the parts.

The interview schedule was divided into four sections. Section 1 served as the preamble (recommended by Kuzel et al, 2003) and included confirmatory details of the participant's clinical role and location, but also the invitation to talk informally about the most recent and memorable error they had experienced, either through direct involvement or as a witness. The interviewer would then ask if there was anything significant from the narrated experience. Section 2 would then focus on identifying and discussing the contributory factors in drug errors. The author's focus on error causation would be initially based on the participant's chosen or *critical incident* (also a technique used in the AIMS reporting scheme for establishing causation and corrective strategies see p42,47), and then expanded to draw out their more general views on error causation. The participant's perspective on any related sensitivities would be explored, the role of protocols and allied to this, the issue of whether some practitioners are error prone and if similar errors appear to reoccur. Views on the double checking process were also to be ascertained which linked to the notion of defences and what participant's preferred defences might be.

It was envisaged that there would be spontaneous dialogue around contributory factors in Section 2 as the preceding narrated experience should have included some comment on causation or contributory factors. In fact, the order of the schedule was often altered as a result of participants' differing emphases in their narratives.

Section 3 was dedicated to reporting drug errors, and served as an opportunity to determine participants' views of the reporting culture. The first open question: *'Tell me about reporting here in the trust?'* was designed to trigger a spontaneous flow of discussion. This, together with asking about strengths and weaknesses of the system, was planned to provide an early appraisal of the reporting process. Further exploration of the perceived culture was to be facilitated by asking about whether reporters could write what they wanted. Any beliefs concerning differences in reporting across the professions would then be examined.

The questions to be posed in the final section would extract information about the existing report's structure and process, in particular their documenting of causation, and experience of action taken. Although all the topics to be covered in the schedule, could potentially inform the design of an enhanced reporting system, these final questions in particular were included to provide the more prescriptive information needed for what has been termed 'actionable outcomes' (Ritchie & Spencer 1994).

The interview schedule (and recording system) was piloted on two occasions with post graduate research colleagues who were also health professionals. The schedule was also appraised by the author's supervisors.

6.5 Procedure

6.5.1 Setting

The author met with the participant in a clinical venue of their choice, which was usually their clinical base, sometimes in their office and on other occasions in a colleague's office. There were four exceptions: interview seven was held in the participant's home as her child was ill, and three of the pharmacists chose to be interviewed in the university as they felt it was impossible to be interrupted in their own base. The participants were always unaccompanied.

6.5.2 Engagement

Participants were informed that the interview would last for a maximum time of 1 hour. First, each participant was asked if they had understood the information sheet and the author's role. It was clearly emphasised that participants' contributions would be anonymised from the point of giving consent, and that all proper nouns would be avoided or deleted. They were also told that a typist would transfer the contents of the digital audio-recording to paper, and she would have no access to participants' names.

The non-judgemental stance of the researcher was also re-emphasised – stressing that errors generally occurred due to systems problems and not personal failings; as recommended by Kuzel et al (2003, p766) in their approach to collecting data on medical errors from health professionals.

Participants were assured that if they were distressed following the interview, they could access the Trust's confidential counselling service, or if preferable - their general practitioner. Finally, it was made clear to participants both in the information sheet and prior to interview that they were free to withdraw at any time and that participating in the study was purely voluntary. Consent for participation and audio (digital)-recording of the interview was then taken.

In an attempt to minimise bias, the standardised probes and supplementary questions shown in the interview schedule were used to elicit greater detail from participants. The approach was informed by the notion of 'active interviewing' (Holstein & Gubrium 2004, p151) where the interviewer should:

1. provoke the respondent to formulate and talk about their experiences
2. converse with respondents in such a way that alternates possibilities and considerations come into play
3. develop topics in ways relevant to their experience

The interview was closed with a clear expression of thanks to the participant. Some of the participants were also asked whether the interview had raised issues which they might wish to discuss further, outside the interview. On just one occasion, time was offered by the researcher following some degree of distress during the interview. It was stressed again that any discussions at this point were strictly confidential.

6.5.3 Transcription

After each interview, the digital recordings were numbered and sent via the university email system to a medical research transcribing typist who returned the anonymised typed transcripts via the same system. As transcription is actually a part of the process of analysis, the researcher should not assume it to be (particularly when another has prepared the transcript) a literal representation of the reality of the interview (Murphy et al 1998). To counter this possible threat to validity, the majority of digital recordings were listened to and compared with the 'typed' interview texts.

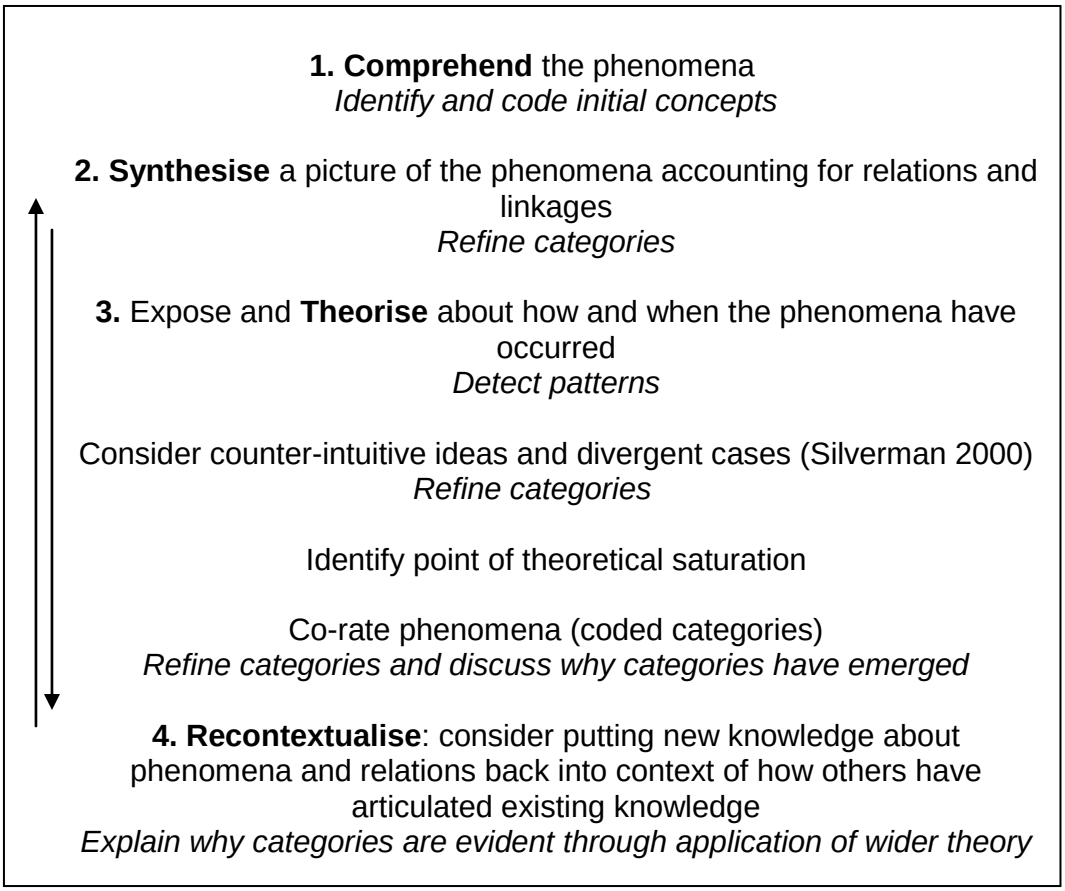
6.6 Analysis

In an attempt to produce an account which gives a favourable impression, qualitative interviewees may present themselves as overtly rational or competent (Murphy et al 1998, p120-1). In this study, the phenomenon may have been exacerbated by feelings of guilt from a previous error for which they felt responsible. Consequently, the interview data was analysed mindful of the *function* of the account, the participant's perspective and context (Silverman 1985), as well as what was actually said.

The systematic process was informed by the principles of analysing qualitative data as described by Spencer et al (2003), further developed by the work of Silverman (2000), and organised into 4 phases originating from Morse (1994). Figure 6.1 below provides a rudimentary flow chart of the process, illustrating Morse's phases,

inclusive of the above principles. The arrows represent the iterative process that is necessary in data analysis, accepting that the recordings and transcribed texts were managed as a puzzle (Mason 1996), working backwards and forwards until the puzzle was disentangled.

Figure 6.1: Qualitative data analysis process (adapted from Spencer et al 2003).



The analytic process began from the commencement of data collection, and was stimulated by keeping a brief diary record of the interviews themselves and the part played by the researcher. Most of the recordings were listened to later on the day of the interview or in the subsequent 48 hours. From this listening process came the first clues that there were profession-specific archetypes.

Following transcription, the individual contributory factors were highlighted together with other recurring phenomena and notable divergences on each transcript. The transcripts were also annotated in their margins and back sheets to memo theoretical propositions, and after the first five interviews some cross referencing [e.g. of contributory factors] was possible.

The data was also initially organised using Nudist QSR NVIVO 2.0. Each separate factor was identified as a free node and memos were created to explore conceptual relations and links between nodes. This seemed to be a helpful first step in managing approximately 200,000 words of text, especially in placing so many contributory factors into a manageable order. However, it became apparent that navigating a way through the transcripts and simultaneously extracting phenomena for category development via a screen image, was leading to some data being inappropriately excluded, and some of the linkages being overlooked. From this point, the data were manually managed rather than managed by software.

Following Silverman's guidance, the data were searched for divergent cases, which it was hoped would assist in the eventual development of a dialectic (Silverman 2000), but more immediately that the irregularity of such cases would substantiate the regularity of the dominant cases (Silverman 2000, Lewis & Ritchie 2003).

Saturation or 'information redundancy', (Lincoln & Guba, 1985) was apparent within the nursing and pharmacy participants before the sample target of 40 was reached. There was less confidence about saturation concerning the junior doctors, who were more difficult to recruit, which resulted in six (out of 15) of them being the last six participants. To increase the objectivity in assessing saturation, the primary categories were tabulated with reference to interviewee number which showed their chronological order. This allowed identification of a *new* category related to either contributory factors or reporting *when* it was raised by a participant (See example in Appendix item 15). This was particularly important in examining contributory factors which were tabulated individually, evidence of which is also available in Appendix item 15 showing frequency of contributory factors by profession.

It has been argued that external co-rating can be too superficial to produce a meaningful analysis (Lincoln & Guba 1985, Armstrong 1997). However, following the final interview co-rating was instigated, the central aim being to gain an

additional or alternative perspective on the data (Barbour 2001). The co-rater (a psychologist and fellow PhD student) was simultaneously conducting another funded study in the same organisation exploring the organisational factors that might predispose to drug errors, using human error theory as a theoretical framework. She was given 6 (15%) of the transcripts, two from each profession, one senior and one junior. There were no other selection criteria. The chronological number and status of the participants concerned are shown below in table 6.2.

Table 6.2: Co-rater's sample of interview transcripts

Chronological number of interview	**Participant status**
Interviewee 02	Senior pharmacist
Interviewee 10	Consultant neonatologist
Interviewee 12	Staff nurse (surgery)
Interviewee 15	Pharmacist (cardiology)
Interviewee 24	Ward manager (medicine)
Interviewee 40	SHO (paediatrics)

The co-rater was first given the raw transcripts, without any annotations and asked to identify key phenomena as categories and consider any linkages. Several days later she was given a separate list of the primary categories as originally identified by the author and asked to appraise these in the light of her independent review. She was also asked to identify which individual contributory factors were substantive enough to be sub-categories.

Re-contextualising the data was not a discrete step as portrayed in Figure 6.1. It occurred from the commencement of data collection (when some passages of text immediately stimulated thoughts about links to the literature); throughout the analysis phase; at the time of preparing the pilot incident report; and with greater theoretical detail when writing the final discussion.

The approach to analysis was also informed by the ultimate aim of the study – to design an enhanced reporting scheme. To this end, that part of the data analysis where respondents offered direct comments on how they felt the reporting system could be practically improved was informed by the *Framework* model for applied qualitative research where the research focus must provide 'answers' (Ritchie & Spencer 1994, p175). Table 6.3 shows the connection between the objectives of framework and their application here.

Table 6.3: Connections between 'Framework' objectives and their application in this study (Adapted from the work of Ritchie and Spencer 1994, p174)

Framework Objectives	**Application to this study**
Identify the form / nature of what exists	Attitudes towards and experiences of current reporting system. Elements of reporting process
Examine reasons for what exists (current reporting patterns)	Factors behind reporting rates, profession-based, and unit-based differences in reporting, understanding of error concepts and terminology
Appraise effectiveness of what exists	Barriers to reporting, opportunities for reporting, expectations
Identify new ideas and processes	Explore modifications to current system, and feasibility.

6.6.1 Rigour: validity and reliability

The validity of interviews should be judged on the basis of how well the inevitable and inherent biases have been tempered. Interview data can be viewed as the situated accounts of individuals who have been asked, on particular occasions, to discuss their feelings, opinions and behaviours. Individual interviews such as those carried out here provided generated (or retold) data rather than naturally occurring data (Ritchie 2003).

Some of the analytic processes referred to earlier in this chapter have been implemented to increase the rigour of the research process, as recommended elsewhere. These were: purposive sampling (Barbour 2001), divergent case analysis (Silverman 2000), co-rating or multiple coding, (Silverman 2000, Barbour 2001), and a clear account of the interpretative methods used to develop the categories and their inter-relationships (Murphy et al 1998).

It was decided to exclude the option of participant-checking even though it has been ardently recommended (Guba & Lincoln 1989). In unison with Sandelowski's change in position from 1986 to 1993, although it seems laudable to offer interview participants the opportunity to consider whether the study's interim findings fit their realities, they may not be best placed to assess the accuracy of interpreted phenomena. Participants may have forgotten the way they dealt with the questions asked, and unlike the author, they have not been immersed in either the data or the wider theory to which it might be allied.

Finally, although there was a corroborative potential between the data from stage 1 and stage 2, it would be theoretically inappropriate to triangulate the findings from two very distinct means of data collection (Murphy et al 1998, Barbour 2001), and of context (Silverman 2001).

6.7 Conclusion

This chapter has presented a detailed summary of the methods used to collect and analyse the data from a series of semi-structured, individual interviews. The interviews were carried out with a multi-disciplinary, volunteer sample of 40 health professionals in their clinical locations. Participant confidentiality was a key consideration. Data analysis was based on a combination of approaches which would consequently allow discussion of the data in relation to the theoretical framework proposed in chapter 4. Although the data was managed by QSR NVIVO 2, concerns about developing a comprehensive and whole analysis led to the adoption of a manual method.

Due to the requirements of the trust and the ultimate aim of the study, the initial analysis identified and described those aspects of the data that would directly inform the development of an enhanced reporting scheme, guided by 'Framework' (Ritchie & Spencer 1994). A cross section of the data was also be subjected to a process of co-rating to generate an alternative view of the data.

CHAPTER 7: FINDINGS FROM STAGE 2

7.1 Introduction

The previous chapter detailed the methods employed to design, implement, and assess the quality of the qualitative interviews. This chapter now describes the findings from the 40 interviews. As previously discussed, the report data (stage 1) and the interview data were intended to be used in combination to design an enhanced reporting scheme.

Two approaches informed the data analysis. As described in the previous chapter, the analysis was largely informed by the principles of analysing qualitative data as described by Spencer et al (2003), further developed by the work of Silverman (2000), and organised into 4 phases originating from Morse (1994). This provided a detailed multi-professional perspective on the contributory factors in drug error, the nature of error, the culture of reporting and the associated inter-professional dynamics. The 'Framework' model (Ritchie and Spencer 1994, Ritchie et al 2003) was also used where the aim was to extract those data that could contribute directly to enhancing the structure and process of the existing report.

Of the primary categories that emerged, the category titled 'Reporting process' yielded the most obvious data to directly enhance the existing system. The findings specific to this category are presented first, as this reflects the chronological order of analysis. The order was dictated by the need to present any planned enhancements to senior management prior to formally redesigning the existing report, and preparing for a piloting process. To avoid the data being based on specially selected fragments to reflect the researcher's view (Silverman 2001:241), where possible, simple counting techniques were used to support any claims made on the data. Following description of the primary categories, a commentary is provided on the co-rater's contribution to analysis which precedes a conclusion.

Figure 7.1: Primary categories from interview data

- Reporting process (structure and outcomes)
- Error orientation (the participants' understanding and supporting beliefs around error genesis)
- Contributory factors
- Defences
- Reporting culture (attitudes, values and beliefs concerning reporting)
- Inter-professional dynamics

7.2 Primary categories

7.2.1 Reporting process

Four sub-categories were apparent from the category of 'Reporting process':

- Strengths of the existing reporting system
- Function and layout of the existing report
- Recording contributory factors
- 'Taking action'

No questions or probes were removed from the original interview schedule. However, responses from participants in the early interviews, largely stemming from questions about whether they could write what they wanted in the existing report, prompted me to ask subsequent participants directly about particular format issues such as 'tick boxes' in addition to the existing free text boxes. This was apparent in one of the early pharmacist interviews where the participant responded by earmarking the advantages of their alternative in-house reporting system:

'the report form that pharmacists use for one month of the year is something a lot simpler in actual fact. Basically it lists the patient's initials, the unit number and the nature of the pharmacist's intervention. So they might write, a doctor prescribed 50mg of X, should have been 5mg, and then you tick a box as to what action was taken, and in that system there is analysis of error types' (5P)

7.2.1.1 Strengths of the existing reporting system

Several participants proposed that the format was easier to complete compared to an earlier system (2SP, 13SN, 18SN, 19SN, 24SN, 27SN), two adding that it also felt more confidential and less about blame than previously, and that the act of reporting errors allowed problems to be brought to the fore (11N, 14PT, 20PT, 25D). Of the staff that discussed strengths, there was just one doctor.

7.2.1.2 Function and layout of the existing report

A key concern here was the difficulty faced by some practitioners in knowing what to report, and to some extent how. Doctors, nurses and pharmacists all commented on the wooliness of *'where the line is drawn [as to what is an error]'* (04P) – which was an early indicator of participants' forthcoming concerns about how the institution might judge an error, but also how there was a lack of consistency (among staff) in the definition of a drug error (24SN); one senior doctor suggested that a meaningful taxonomy might create consistency and that this would be an important consideration in generating any enhanced reporting scheme (8SD). Critically aware of the phenomenon of being unable to report everything, another senior doctor (10SD) proposed that staff should be encouraged to differentiate between the potential of an error to do harm and when harm is actually done, and that the report structure could add guidance on this. A senior pharmacist felt that detail in both the circumstances and how the error was 'rescued' (how patient harm was avoided) were imperative (2SP).

It was clear from the responses that a majority of staff wanted more simplicity, yet paradoxically they wanted the opportunity to report more detail. Particular advantages of tick box options were volunteered: they were seen to serve as prompts, as being helpful to international staff or juniors; and promote a better understanding of the language of medical error (and risk management). In fact a clear majority of participants were supportive of tick boxes for error types and

contributory factors. While many participants wanted the option of tick boxes, most were equally keen to keep the free text, their various rationales also acknowledged the importance of context in drug errors: *'They often have complicated causes'* (16SN), '*each case is individual'* (23SN), and for one junior nurse:

'you want them to know the ward was busy, you were short staffed, Mr. X was unconscious and he didn't have an allergy band' (17N).

A tick box format was also seen to have disadvantages. A reporter cannot emphasise how one contributory factor may be more influential than another (29D), and some reporters may feel threatened by a box labelled 'fatigue' (35D). The responses concerning the use of tick boxes for error types and contributory factors are quantified in tables: 7.1 and 7.2.

Table 7.1: Responses concerning tick boxes for error type (not all offered an opinion, even with probing) in a reporting scheme

Response	**Doctor**	**Nurse**	**Pharmacist**	**Totals**
Yes	8SD, 9SD, 10SD, 25SD, 26D, 29SD, 31D, 36D, 38D, 39D, 40D	1N, 3N, 6N, 12N, 18SN, 19SN, 23SN, 24SN, 27SN.	2SP, 4P, 5P, 30PT, 34P	**25 (62%)**
No		16SN		**1**
No comment	7SD, 21D, 35D, 37D	11N,13SN, 17N, 22N, 32N	14PT, 15P, 20PT, 28SP, 33SP	**14**
Totals	**15**	**15**	**10**	**40**

Table 7.2: Responses concerning tick boxes for contributory factor in a reporting scheme

Response	**Doctor**	**Nurse**	**Pharmacist**	**Totals**
Yes	9SD, 10SD, 25D, 26D, 29D, 31D, 36D, 38D, 39D, 40D.	3N, 6N, 12N, 16SN, 17N, 18SN, 19SN, 22SN, 23SN, 24SN, 27SN, 32SN	2SP, 4P, 5P, 30PT, 34P	**27 (67%)**
No	8SD			**1**
No comment	7SD,21D, 35D,37D	1N, 11N,13SN	14PT,15P, 20PT 28SP, 33P	**12**
Totals	**15**	**15**	**10**	**40**

7.2.1.3 Recording contributory factors

Participants responded quite energetically to the question of who should record contributory factors, which may have indicated a need to acquire some ownership of the reporting process. While one junior doctor felt this was a task that predominantly fell to nursing colleagues or the person that *discovers* the error (26D), half of the participants felt the protagonist should be the person completing this section, but notably several added that this should be with the help of another – preferably a senior colleague or manager – who was thought to be able to provide the bigger picture. Several nursing participants incorporated the emotional needs of the protagonist by suggesting *'some people need to write a full explanation….everything to get it off their chests'* (24SN). Furthermore, a senior nurse added that *'you must put your whole story across….rather than just….going she's made a mistake, now let's get her in and tell her off'* (17SN). Two practitioners claimed it didn't matter who filled it in *'as long as they understand the process they're contributing to'* (08SD). Table 8.3 shows the participants' opinions on who should record contributory factors.

Table 7.3: Responses concerning who should record contributory factors in a reporting scheme

Response	Doctor	Nurse	Pharmacist	Totals
Protagonist	7SD, 26D, 31SD	1N, 3N, 11N, 12N, 17SN, 19SN, 24SN	5P, 15P, 20PT	13 (32%)
Protagonist + manager	9SD, 10SD,	6N, 13SN, 32SN	2SP, 30PT	7 (17%)
Manager	21D	23SN		2
Discoverer of error	25D, 29D			2
Irrelevant as long as you understand the process	8SD		34P	2
Two opinions are necessary	35D, 36D, 37D, 38D			4
No comment	39D, 40D	16SN,18N,22SN, 27SN	4P,14PT, 28P, 33P,	4
Totals	**15**	**15**	**10**	**40**

7.2.1.4 Taking action (after the error)

There was strong support especially among the medical staff for local rather than organisational wide action, unless an error had catastrophic consequences (8SD, 10SD, 21D, 36D, 38D, 26D):

'I feel that if I am given a chance I would grade incident reporting into two forms. One which could be sorted out locally, but there should be a person who should be responsible for that, who should be more experienced in the ways it is to be dealt with. Ordinary things can be dealt with locally. Say, for example, something happens here, a consultant should be able to come and speak to that particular person and sort it out. It should go into the record, but should go very informally. And there's other ways, the other one, which is the severe one, should go centrally monitored. So there should be a person who should be able to delegate…..to be able to differentiate these two and deal with it accordingly. (21D)

The two senior doctors (8SD, 10SD) came from units where the discussion of reporting was highly valued – *'we need discussion as the warp and weft of the place'* (10SD), and it was notable that their nursing colleagues took a similar view:

'Well, a local management type person and a clinically based nurse [should be involved in action taken]. Some of the Neonatologists are in the Incident Group and then we've got several junior staff that we try to involve as well. We try and work through the incidents and then there's a newsletter that comes out shortly after the Incident Group so people get feedback of what drugs, and a sort of a top ten….. it's always drugs. So drug errors are number one in the top ten. They're not usually complaint things, but niggly little bits. And then obviously there's the wider remit, the Paediatric and Obstetric Clinical Risk Groups that we're involved in and we get some feedback from that but I think there it stops'' (22SN)

Lack of feedback from action taken also concerned the most senior nurse in the

sample. She had previously acknowledged the difficulties faced in feeding back to every reporter and while accepting the system could be improved in this way, she believed this was everybody's responsibility. By implementing some local system this might reduce the likelihood of individuals criticising the organisation about the nature of feedback as well as capturing some useful analysis:

'I think the feedback has to be much more local because what are they wanting in feedback? I've asked this question of staff myself because they say this to me when I talk to them about reporting: 'Well, we never get any feedback.' 'OK. So what sort of feedback do you want then?' 'Well, we want to know what happened.' 'Well, it was your incident. What did you do about it then? How did you use that to improve either, A, your practice or the team's practice? What have you done? Hang on, what's this feedback?' I think there is something about feedback and there's something about analysis and being able to flag things to people to help them to focus perhaps on areas of practice that could be examined in more detail. If something's happened in one area but not in yours and may do very soon, then it's an opportunity for you to look at that before it becomes a big issue' (32SN)

While it was clear from 7 participants that how the patient was affected should strongly influence action taken (3N, 7SD, 12N, 19SN, 27SN, 31D, 36D), more staff saw cited the need for staff support and feedback (1N, 5P, 6N, 7SD, 16SN, 17SN, 19SN, 20PT, 23SN, 30PT, 31D, 40D); their general argument being that unless steps are taken to reduce the likelihood of the error reoccurring by being fair-minded and promoting learning with those involved – the reporting process can be futile:

'When you do an incident form, even an acknowledgement just to say, 'Your incident form has been received. We are addressing it, then people are going to think: oh, something actually happens to them. Something happens with the information that's provided. And I think that'd make people more likely to fill one in,

having some kind of an idea of the incidents that do occur within the Trust, because on one shift you might have an incident and no-one else will ever hear about it. So I think if we had some kind of Trust-wide instances of drug [errors] and what kind of errors were made, how often they occur, we'd be more likely to be open about reporting them, because people can see, oh, it's not just me that has made this error.' (19SN)

It was asserted by the most senior nurse interviewed that any analysis, whether at the time of the incident or afterwards is superficial and often inappropriate (32SN), and by three others that analysis of the error was an essential element of action taken (10SD, 23SN, 35D). Overall, 65% of participants suggested a separate, designated form for drug errors (Table 8.4); a point raised spontaneously by the first participant:

(GA) From what you know about the reporting system here, what sort of improvements would you like to see in it?

I would like to see a separate form for drugs. I would like to see a bigger space for you to actually write what's happening. I think on the current one we've got now, it's like for everything, isn't it? And you end up just dashing some of the boxes because they're not appropriate' (1N)

The pharmacists in particular were keen to move from a generic to a specialist reporting form, largely because they were actually able to compare two types of form as a consequence of also having access to the in-house system previously described:

'Why should a drug incident be anything like a patient attacking a member of staff? It's an incident but everything about it is different and the results that you want to achieve are different, aren't they, from a patient falling out of bed. Again, it's too different. I want to fill in the incident form so that awareness will be raised of that incident and that that knowledge then can be used to improve processes or group

knowledge' (34P)

Furthermore, several respondents across the professions suggested alternative ways of reporting such as telephone, or via the intranet, however just three nurses and a doctor proposed an anonymous system.

Table: 7.4: Responses to the specific question: Would you envisage a separate reporting process for drug errors compared to other errors?

Response	Doctor	Nurse	Pharmacist	Totals
Yes	10SD, 21D, 25D, 29D, 31D, 35D, 36D, 37D, 38D, 39D, 40D	1N, 3N, 6N, 12N, 17SN, 19SN, 24SN	2SP, 4P, 14P, 15P, 20PT, 28SP, 30PT, 34P	**26 (65%)**
No	7SD, 8SD, 9SD	13N, 23SN, 27SN, 32SN		**7**
No comment	26D	11N, 16SN, 18SN, 22SN	5P, 33SP	**7**
Totals	**15**	**15**	**10**	**40**

7.2.2 Error orientation

The intention of this category was to capture the all the various comments, so as to construct a clear picture of participants' beliefs and opinions on the genesis of error. It was clear there were inter-professional differences, and for this reason the responses are ordered by profession. For example, the nursing participants had an individual orientation to error which diffused into their approach to reporting. It was also evident both in this category and that of 'reporting culture' that there were deviant or negative cases. Valuable insights were gained though analysing the first phase of the interview where participants were invited to simply narrate their most recent experience of a drug error.

7.2.2.1 Nurses

The nurses' narratives were notable for their inclination towards individuals rather than systems, the participants were not infrequently self-admonishing which was also recognised by a pharmacist who described nurses as being *'much more critical of themselves if they transgress'* (15P). They often used very personal

language and sometimes added, following a described error, that they would not make the same error again:

'how stupid I was that I didn't click that there was a prescribed medication as well,… I had a blonde moment…I overlooked something which I've never done before, nor will I actually ever do again' (1SN)

'[I was] frightened to death I'd harmed the lady because she'd taken medicines that weren't for her, so paranoid that she was going to die as a result of it' (23SN)

'you feel gutted if you've made a mistake, and if people find out, you feel ashamed' (6N)

Underpinning this was an obvious sense of accountability, yet not just specific to their own practice but emanating from the acts of other professionals; the nurse above claimed that her length of experience actually made her accountable for others such as junior doctors:

'you're still accountable aren't you for the amounts of stuff that you've given because you're probably more experienced than the doctor writing it' (6N)

The 'blonde' metaphor was also used by a senior nurse from a high dependency area who described an error that had evaded the double checking process, and then drew the following conclusion but about her colleagues:

'For me, it's just blond hair. It's just taking it for granted, that what they're doing is correct without actually thinking about what they're doing. (13SN)

The notion of cognitive difficulties will be discussed later, though as a contributory factor, however it was sometimes difficult to ascertain whether it was deemed to be an attitudinal problem, or strictly cognitive:

'90% [of errors] are to do with the individual's lack of concentration and invariably, in my experience, when you ask somebody, 'Why did you do that? Why did you

give that?' they'll say, 'I wasn't thinking,' or something of that sort'

(16SN)

This generally individual-inclined perspective did not mean that the nursing participants focussed on single causes in their interviews, there was a strong suggestion that even when cognitive problems were involved, the error arose from a combination of factors:

'I think sometimes there's a lot of things that contribute to drug error. I'm just talking of a few of them…..where you're used to giving something as a certain dose or a certain weight and then it gets written up slightly different once…you see what you're used to seeing……I think usually there's more than one thing contributing to drug errors. Like we were talking before, there was the prescription that was misread and also the lack of experience there and the knowledge so there's more than one thing that can lead to a drug error' (27N)

The participant in interview 12 was the exception to the generally consistent nursing view, perhaps representing a deviant case. In common with the others, he discussed error causation in an individual context but was isolated in explicitly declaring his own registration as paramount - rather than the patient's well being:

'you're looking after yourself as a primary issue, your patients are important but it's your own registration, your own livelihood' (12N)

7.2.2.2 Doctors

The first four interviews were with consultants, who like the nurses, largely cited errors in which they had been instrumentally involved. The consultants, however, took a more cautious and dispassionate view. While they demonstrated considerable insight into their own limitations (07, 08, 09, 10), they were self-assured, unlikely to incline towards self-chastisement and ever-ready to acknowledge the multi-factorial nature of error causation. The typically lengthy quote from the consultant below illustrates a number of the above characteristics:

'One of my junior staff had prescribed an as required dose of a painkiller for one of the patients and I had decided it was the wrong drug and the wrong dose but it hadn't been given. He'd only just written it and, as a team, we decided that we would change it. Now, instead of following the written rules, scoring out what he'd written and rewriting the whole thing again, I scored out the name and put the proper name and signed it, and then the dosage that he'd actually written was going to be the same dose for this new drug and so I initialled the dose to say that's the one I want to be given and I thought I'd done it pretty well. Now when the nurses came to give that drug, they mistook my initials beside the dosage for a change of dosage. So that was an interesting one, wasn't it? Now we've got a good team and that came back to me so that I was able then to say, no, no, that's my signature…..

Because they thought, it's really strange of [name] to do it this way. We think it's a change of dose, but we can't quite make out what she's written. And that's unusual because I usually print so that they can know with confidence what I've written. That's not to say my handwriting in general is good. So because it was unusual for me, it was picked up. And if that wasn't picked up, then they would have made some sort of decision about what I'd written and given that different dosage. So that's my fault for not following the written guidelines, which very clearly say if you're going to change a prescription in any way at all, you score it out and you write a new one. Because this was a drug that hadn't been given yet and had only just been written, I thought, well, this is all right to do it this way. But clearly not, that is now going to be reflected in my teaching of the junior staff and I can say, look, I'm very experienced and I got it wrong' (07SD)

The language here is less emotive and although the participant accepts 'she got it wrong', the lessons learnt are not couched in terms of personal failure but rather learning. Below, another oncologist reflects on a recent near miss related to a potentially lethal incorrect dosage of chemotherapy. He then discussed causation

as been related to inappropriate cognitive processes, adding notably, that correct decisions cannot be made all of the time:

'what keeps it in my mind is that I could have done somebody some harm really, and that it was a pretty basic sort of error, [one] that I would have been really fed up to have made a few years ago when I was much less familiar with what I do, and to still make it now. One makes sort of, if you like, judgements that with hindsight, one isn't comfortable with every so often….and you weigh them up and you say, well, on the balance of things, it's right to do thing A not thing B. But you know that you could do thing A and it would work out five times in ten, and you could do thing B and it would work out right three times in ten. Neither of them is going to work out right ten times in ten….but you just gave it your best shot and it didn't work out. In one sense that's an error. In another sense it isn't, it's just what it's like looking after people with cancer really' (08SD)

The junior doctors were like their senior counterparts in that they shared a similarly rationalised view of error, one SHO directly referring to its inevitability – *'there's nothing I could have done to avoid it really'* (26D), that *'doctors are considered to be knowledgeable in every field but they are not'* (21D). Another SHO perhaps sheds light on how this view is reinforced, concerning the prescription (and subsequent administration) of amoxicillin to a penicillin-allergic patient, she was 'just asked' to speak with her consultant, a not uncommon approach within medicine:

'Yeah, there wasn't anything on the front of the chart and I couldn't ask the patient themselves because they were poorly. So I wrote them up for some oral amoxicillin and luckily nothing happened, you know, there was no rash, there was no adverse effect. But the nurses didn't pick up on this either and they administered the drug for about three or four days, and then it was only after that that it emerged that he was penicillin allergic. And then an incident report was filled in and I was just asked

to speak to the Consultant, which we went through, and, yeah, it was fine' (37D)

Indeed the junior doctors talked far more about *discussing* errors with their colleagues – the informal nature of dealing with errors also included a strategy for prevention – concisely summed up by one SHO who claimed *'we tend to keep an eye on each other'* (35D).

7.2.2.3 Pharmacists and pharmacy technicians

The context of pharmacy work is largely different from that of nurses or doctors. While they have specific clinical responsibilities which involve visiting wards and amending patient documentation, they are unlikely to engage *directly* in patient care or the *actual* delivery of a drug - other than in their dispensary work with out-patients.

Importantly, both in the pharmacy (through the clinical check) and in the ward areas, pharmacists have a strong monitoring role, and through this detect many errors:

'Yesterday on my ward, a new patient had been clerked in and had a drug written on their chart which was nifidiprel. Now this drug doesn't exist and so I had to try and work out what it should be and, by going through the medicines that the patient brought in, realised that the drug that the missing drug was called clopidogrel, this patient had come in for an angioplasty procedure and this drug was quite critical after the procedure. So the patient came in on it, would need it during the procedure and after the procedure but, because they'd been clerked in incorrectly, the patient hadn't had it on the day after the procedure. So I was able to get the doctor to change that and ask the nurse to give it at 1 o'clock. Even though it was four hours late, at least the patient got it that day' (15P)

Furthermore the pharmacist's work is obviously centred on drugs and consequently they speak in extensive detail about drug errors:

(GA) I wonder whether you could just talk through that error? Is that OK?

Sure, yeah. Well, the most recent one was when I visited a ward this morning, and requested to re-supply some medication which had been supplied yesterday. So I queried why I was being asked to re-supply it and as it transpired, to cut a long story short, it revealed that too much of the amount supplied yesterday had been given this morning. So it highlighted an administration error which hadn't been picked up previously.

(GA) So, found as part of your daily duties, shall we say?

Yes.

(GA) And what sort of drug was involved?

That was intravenous phenytoin, and the specific instance was five ampoules were sent yesterday. The strength of the injection is 250mg in 5ml. The patient's dose was 100mg IV three times a day, and at the time I thought ten were sent yesterday and so I made some further investigations. Only five were sent. But when I said, well, ten were sent yesterday, a nurse said, well, that's not very many, we gave four this morning. So four 250mg would have been 1g, when the patient should have had 100mg' (5P)

It is perhaps their difference in role (and context) that influenced their narrations of drug errors which were almost always grounded in a systems approach. Here a senior pharmacist describes her experience of how drug errors manifest:

'The flow of work through a department tends to be that it's quiet at the beginning of the day and gradually builds up towards the end of the afternoon and then it goes manic. We have put all sorts of systems in place to control the flow of work to try and level it out throughout the day' (02SP)

However, this didn't mean that they were completely dismissive of the human contribution – although again it was related in terms less personal than those employed by the nurses, and human frailty was also acknowledged:

(GA) Do you think certain people make repeated errors because of their make-up or their circumstances?

I'd say that's probably true, yeah.

(GA) Any thoughts on that?

'I think it's interesting to pursue the idea that why, once an error starts, it compounds itself as it goes down the chain. And is it autosuggestion or is it that it sets off a pattern of brain activity that replicates itself as it goes down the line? It's almost as if, you know, if you've got somebody who's slightly dyslexic in the system who gets things crossed over, that sort of propagates itself. And I can't explain it, but you do see it happen. Where you've got things which need to be matched up or where you've got things which have to be transferred across, we do a huge amount of error or mistake correction on the clinical checking desk in the pharmacy and we'll have passed it on the way in. And when you look at simple transcription errors from what the doctor had written on the chart to what the nurse writes on the request sheet and that then gets transcribed down to something that pharmacy dispenses, goes back to the ward and gets given to the patient by a different person again, and you can start with a horse and end up with a camel' (15P)

The pharmacy technicians, although the pharmacists' immediate departmental colleagues, spent the vast majority of their time within the pharmacy. They work at a fast pace, in a confined space and carry out predominantly repetitive actions on what could be described as a medication production line. The pharmacy technician below described how an error occurred, but again quite systematically:

'(*GA) What sticks in your mind about that error, anything in particular?*

It's an absolute classic. As it turned out when they've gone to the drawer to check stocks they've found a previously dispensed box, not an original container, we do try for people to not put dispensed packages back into stock. We prefer if anything's going back in the drawer, it goes back in its original container.

(GA) Explain that to me. Does that mean there are two ways of storing stuff?

No. So like when we dispense something, often we're not giving it out in original packs. We often split the packs down. So we'll dispense them into the little white cartons, into little white dispensing cartons.

(GA) Hospital cartons, yes.

Yeah. So they're just a plain white carton with one of our labels on the front of it. Sometimes the medication is not needed by the patient and it will come back to us but we tend not to return those boxes back into our stock. They will be disposed of because of the risk - you haven't got an original container to look at' (30PT)

From an initial inspection of the data, three quite distinct profession-based images emerged. The nurses seemed to be less confident about being involved in error, frequently being self-critical and allied to this, sometimes made unrealistic demands on themselves. Their perspective of error was often grounded in the context of prolonged patient contact. The medical staff took a more measured view of error. They were conscious that any human contribution was part of a whole range of factors that might contribute to an error, and that errors were inevitable; their initial narratives also frequently demonstrated a confident pragmatism about the genesis and consequences of error. This mindset seemed to be reinforced by the way in which human error was managed within their discipline. The pharmacists were somewhat different again. Although their context was treatment like their medical counterparts, they were relatively separate from purely clinical encounters with patients, which may make them feel less a part of the clinical team. However, they are instrumental in medication management, have a predominantly systems orientation to error, and as such are notable drug error detectives.

7.2.3 Contributory factors

Seven contributory factors were identified as principle sub-categories, having sufficient data to generate detailed descriptions. Table 8.5 shows the factors, and

also indicates the number of times the factor was raised by different professionals and is illustrative of the attention given to the factors across the sample. In relation to 'double checking' which was usually an a priori category having stemmed from a specific question in the interview schedule, the count only demonstrates how many participants believed double checking to be a contributory factor rather than (as was expected) a defence. As the only factor that was strictly a priori, it is discussed last.

Table 7.5: Principle contributory factors: number of times cited by participants, by profession

Contributory factor	**Doctor**	**Nurse**	**Pharmacist**	**Totals**
High Workload	7SD, 9SD, 21D, 24SN, 25D, 26D, 29D, 31D, 35D, 37D, 39D, 40D	1SN, 3N, 13SN, 17N, 19N, 23SN,	2SP, 4P, 5P, 14PT, 20PT, 28P, 30P, 34P	26
Communication deficits	8SD, 10SD, 26D, 29D, 36D, 37D, 38D, 40D	3N, 6N, 16N, 23SN, 24SN, 27SN, 32SN	5P, 30P, 33SP,	18
Interruptions and distractions	7SD, 10SD, 25D, 40D	1SN, 3N, 6N, 17N, 18SN, 23SN, 24SN, 32SN	2SP, 4P, 5P, 15P, 20PT, 34P	18
Knowledge deficits	29D, 35D, 36D	12SN, 16SN, 18SN, 19SN, 22SN, 23SN, 24SN, 27SN	14P, 15P, 28P, 34P	15
Faulty cognitive processes	7SD, 8SD, 26D, 38D	3N, 12N, 19SN, 13SN, 27SN	2SP, 5P, 14PT, 15P, 30PT, 33SP	15
Inappropriate attitudes	7SD, 8SD, 29D, 36D, 39D	12N, 13SN, 16SN, 17N, 19SN, 22SN,	34P	12
Double checking	9SD, 10SD, 21D, 26D, 29D, 35D, 37D, 39D, 40D.	1SN,3N, 6N, 11N, 12SN, 17N, 18SN, 19SN, 22SN, 24SN, 27SN, 32SN	5P, 14PT, 15P, 20PT, 28P, 30PT, 33SP, 34P	29
Totals	45	52	36	133

Table 7.6 shows the less prominent contributory factors, judged to have insufficient data to form free standing categories. Again the number of times the factors were raised by participants (and their discipline) is shown to illustrate any differing

professional focus. This hierarchy of categories does not mean that the less substantive categories are not important in developing a range of contributory factors, but the less substantive categories held insufficient data to offer vivid descriptions of the phenomena concerned, and on the basis of this sample's view, were less dominant factors.

Table 7.6: Less prominent contributory factors: number of times cited by participants, by profession

Contributory factor	No. of Doctors	No. of Nurses	No. of Pharmacists	Totals
Lookalike/soundalike drugs	2	0	3	5
Labelling problems	1	1	2	4
Polypharmacy	4	0	0	4
High noise and poor light	0	0	3	3
Arithmetical/calculation errors	2	0	0	2
Fatigue	1	0	1	2
Totals	10	1	9	20

7.2.3.1 High Workload

High workload was a dominant category, spontaneously raised by a considerable number of participants and often discussed in association with a sense of chaos. However, it is apparent that high workload was also seen by some participants as a necessary cognitive stimulus. The first participant talked at length about workload, as she recounted what she described as a typical situation which could culminate in an error:

(GA) Just talk to me about what chaotic means in the context of a drug error. Just paint the picture for me.

'It could be a drug you're not familiar with….you've got to read up about it, you've got to check the dose. If you've got to make it up, you've got to be sure you know how to do that correctly. They're all constraints on your time. You might not feel competent to do it on your own…..so if you're seeking someone else out to help then that's commitment away from the ward. Getting the equipment you need, checking it, and continue checking right to the point of administering if they're not

sure, and perhaps that's just because they're tired or because their backside hasn't touched a seat literally for the last five hours, and we're human……..is that what you meant?

(GA)Yes, carry on.

Oh, and buzzers and the phone going and a mum wanting to talk to you, all of which are acceptable but what do you do first? Do you answer a phone, do you answer a buzzer, do you answer an intercom, do you feed a baby to help it go to sleep? You sometimes literally don't know where to turn first. And then you get into the drug room and your mind's still racing and you're still thinking about something you've got to do two hours ago that you still haven't done and it's just oh, woe is me!

(1SN)

The image is one of nurses *'running round and doing medicines at the same time'* (3SN), often engulfed in the personal business of healthcare, and without the defence of any automated safety guards. Another senior nurse from an elderly care setting emphasised that nurses had sustained the brunt of changes around junior doctors' working practices, and like her colleagues, most who mentioned workload mentioned it first:

(GA) What, in your opinion, are the key contributory factors that give rise to drug errors?

Pressure, too much work and not enough staff to do it. The nursing staff are taking on more technical work than we've done before but we haven't let go of any of the work that we were doing before. Because of reducing the doctors' hours, we've picked up IV drugs and we do that routinely but we've not lost any other jobs to pick up that, so there's more pressure on the time (23SN)

However, the most senior manager in the sample when asked about contributory factors did not accept that a high workload was so influential but *how* workload was

managed was critical:

'Workload – [but] I think that just needs to be qualified slightly in that not so much the actual workload but how the workload is organised, I think that's one of the key things in terms of being able to prioritise and manage it in an active way' (32SN)

A point to which she returned:

'There's always, of course, workload - the pure busyness of a place. The throughput of patients is such that, you know, the occupancy of the beds, I mean, they're just never empty and we underestimate, I think, sometimes, just what impact that does have on people because if you're constantly trying to think quickly, then you maybe approach everything with that mindset and really in a way medicines, you do have to be a little bit more perhaps thoughtful and considered and a bit more systematic, and maybe that's hard to change that mind from one way to another so quickly maybe' (32SN)

Three junior doctors (25D, 37D, 40D) believed that it was nurses who were the most likely group to experience a high workload:

(GA) Any other contributory factors?

'Lack of nursing staff. These nurses are rushed off their feet. They've got 30 patients to administer drugs to and they've got other things, you know, patients are bothering them on their drug rounds and it's quite a big factor' (37D)

However, on further exploration this was once again thought to be complicated by particular ways of working:

'I mean, the nurses have got four drug rounds, once a day. And I mean, some of these patients, they'll take their tablets with a cup of cocoa before they go to bed, and especially the Parkinson's patients, they need their tablets at a certain time and the nurses, they don't seem to understand this because they work to a rota, you

know, you get your drugs when they go on the drug round, and they're very reluctant to give drugs at any other time' (37D)

Furthermore, two junior doctors (35D, 37D) also held that a low workload could adversely affect concentration levels:

'I do find that if I'm in a job where things are slow, it's not very busy, not very acute, you do tend to switch off. You're not quite on the ball, so to speak, whereas if you're rushed off your feet, if it's hectic, you're more alert to everything that's going on. I have found that' (35D)

An experienced pharmacist (like several of his pharmaceutical and medical colleagues) gave witness to the pressures faced by nurses, but also acknowledged the complications of a minimal workload:

'I go to the wards to see nurses, who can be under pressure at times.. I mean, I know from personal experience that when people are under pressure, they're more likely to make mistakes. They don't read things as accurately perhaps as they would do at a more leisurely pace. I mean, I think you've got to strike a happy balance really in terms of leisureliness because leisureliness can breed almost familiarity and people start chatting and they get distracted for other reasons' (28P)

The pharmacy staff commented on their own departmental pressures. Pharmacy was described as an extremely busy place somewhat at the mercy of demand, possessing clear operating procedures but with marked crescendos of activity at certain times of day which directly impacted on staff performance in spite of proceduralisation:

'The flow of work through a department tends to be that it's quiet at the beginning of the day and gradually builds up towards the end of the afternoon and then it goes manic. We have put all sorts of systems in place to control the flow of work to try and level it out throughout the day, but we're still faced with the situation whereby

we feel that the volume of work that's coming through is really too great for us to do that work in a systematic way which would prevent error' (2SP)

7.2.3.2 Communication deficits

Participants actually described communication deficits in three forms: local verbal and written miscommunication, trust or unit wide miscommunication, and patient-professional communication. Although discussed as a separate category, communication deficits were also described as an outcome of high workload, and a precursor or outcome of interruptions.

Communication deficits in inter-personal communications frequently drew on cross disciplinary examples, some of which illuminated inter-professional tensions and the perceived status of certain tasks, here between nurses and junior doctors:

'I ask the doctors - can you just go over this pharmacy chart from the ward to make sure there's nothing you want to add to the …' [they say] 'Oh, we're too busy now. I've done it. Just do the one that I've done.' But there might be something that they've missed on it, you see. So that, I feel, was a funny move, and it's generally felt that they don't like these new type of charts at all'

(GA) What's the psychology, in your view, behind this?

I think a lot of them don't like having to write things down all the time or prescribe things. It's enough that they've said to you, 'Give this' or 'Give that'. To them that's over. I don't think medical staff appreciate the importance of written stuff, because it's the same when you get consultants calling or other teams come in and you'll say, 'Have you written what you've just told me in the notes?' 'Oh, just—', you know, or they get annoyed and they write a few sentences. They don't like writing stuff for some reason. I think they feel their job is more hands on and not this administration stuff. But that's not all of them, but most of the problems in this department are, I would think, to do with badly written prescriptions (16N)

And similarly again, on this occasion by a senior nurse:

They haven't got a black pen. They haven't got time, they're rushed. They've got other things on their mind. People are at them all the time. To get over that we did like a work list, so we weren't nattering them all the time but then I expected that list to be done by the end of the day. We get senior house officers on here and they see that as a house officer job, as a menial task. I've tried to get over to them, this is part of your role and a key element to our team working' (24SN)

Once more, communication is seen to be a root problem, but this time between nurses and a range of medical staff grades:

'One of the sections of one of the wards that I look after has orthopaedic patients in and there is no support from their consultants at all. I have no relationship with the consultants from Orthopaedics and I don't think they'd know who I was if I fell on the floor in front of them.

(GA) So this has an impact on the way in which errors arise because of this difficulty in challenging someone's prescription and maybe an impact on the way errors are managed?

Yeah. Because if I know that the way something's been written up is incorrect, either it's the wrong drug or it's the wrong time or it's the wrong dose, I'm quite happy to go to any of our doctors and say, 'I'm really sorry but we normally give this drug in this manner.' But it will be ignored. I'm—

(GA) Sorry to interrupt you. Just to clarify, is that across the staffing grades as well? So you might take that to an SHO because it—

I think it depends on who their consultant is, because some of them will say, 'Oh, so-and-so prescribed it. I can't change it.' And I'll say, 'But it's wrong and I am not administering it because I know it is wrong' (23SN)

Two consultants and an SHO who had previously been a GP strongly believed that

prescription handwriting and copying could be improved, and as previously mentioned, so could the circumstances surrounding the process. It was also felt that the prescription forms themselves should be tailored to meet specialist requirements:

'we'd rather have a chart where maybe it was only a week's worth at a time but there was more room to write down your dose, and how you want it doing and what range of doses was allowed and so on. It's probably different in different areas of the organisation where you might have patients in for a long time and they're anti-hypertensives or something. It's better to have them written up once a month rather than rewrite the anti-hypertensives every week because there's potential for errors occurring in stuff that keeps being changed but for us we'd rather have more space to document more clearly what is actually happening and what we need there' (10SD)

Four junior doctors were very self-effacing about prescription writing, admitting there was much room for improvement, as in the example below:

'So many times that on the ward round we write things up and there's no nurse there and sometimes it's up to them to go through it……I think we need to document and explain what you want, not just write it on a piece of paper. It has to be clearly presented to them and they need to say, 'Right. I've understood that,' and sometimes repeat it back to you because there's obviously a bit of a language barrier with some nurses and as long as they repeat it back to you, then we know that they know what they're doing…..there's a lot of things that we abbreviate that we probably shouldn't abbreviate. I mean, I always, I was taught as a house officer to write micrograms instead of putting the µ and then g, and if I ever see anyone writing µg, I'll tell them even if it's my colleagues. I'll say: 'Look, you shouldn't be doing that.' Because, I mean, everyone's handwriting is fairly appalling really and it can be very easily mistaken if a nurse has never given it before. She could read

that as milligrams and give a ten times a hundred times more dose, illegibility is a big issue' (36D).

It was also notable that there were some concerns about status being a barrier to error defences in doctor to doctor communication:

'…..a consultant will say, 'Put this patient on cef and met.' By the 'cef' in that, do they mean cefradine? Do they mean cefuroxime? Do they mean cefotaxime? And it depends upon either the subspecialty of Medicine or Surgery that you're working in, which one of those they tend to mean and whether it's going to be oral or intravenous, and that's a fairly common sort of area of ambiguity.

(GA) What about the response, 'Well, which cefradine do you mean? Is it IV or oral?'

Yeah. I think often people feel unnecessarily that they can't question what people mean by it.

(GA) I thought you might be getting at that.

In fact usually it's fairly obvious either from the context or because you know what everybody else has been put on, on the ward round. Or I still ask people, 'Sorry, can you just clarify which you want to be prescribed?'

(GA) But there is still a feeling that sometimes, not absolutely certain about –

I think pre-registration house officers often feel that they are supposed to know things and feel that to stop and say, 'Well, actually, I'm not quite sure what you mean by that,' will be frowned upon, as though they ought to know. And I think, although some consultants perhaps give that impression, I'm sure all of them would prefer that they're asked rather than somebody gets given the wrong medication. I think timidity of junior, very junior doctors is sometimes an issue where they feel afraid to ask things' (26D)

The pharmacists' comments, based on their everyday inspection of prescriptions,

affirmed the opinions of the junior doctors, and also spelt out the consequences for nurses. However, one pharmacist was incensed at what he described as the example set by consultants, at which point he physically presented a number of actual prescriptions as examples, asserting:

'Here are prescriptions written by consultants. Severely allergic to penicillin, but recorded 'no known drug allergies'. Allergic to aspirin, no known drug allergies. The great and the good in this Trust writing, crap prescriptions. You'd give a junior doctor a bit of hammer, but these - there you are!' (33SP)

A small number of doctors had remarked on staff who might not have English as a first language, but one of only three participants raised this as an issue. Notably the pharmacist who also declared a similar concern appeared embarrassed as a consequence – her language reflecting this:

'I think there is an increasing problem in that we've got — I don't know whether this is totally fair, but we've got a larger number of Filipino nurses now and they do seem to have more problems. I seem to notice more problems with them not recognising things and knowing what they are and being able to find them' (34P)

Three other junior doctors (26D, 37D, 38D) did however air their concerns about difficulties with patient communication which they felt were sometimes hampered by language differences, as well as an underpinning (trust wide) systems problem:

(GA) Clerking can become a real issue?

Really difficult. It's really difficult.

(GA) You might not have the [medical] notes immediately, the old notes as it were.

Yeah. Well, we never do. We always get them the next day, so it is really difficult. So we've just got to go on the presumption, and don't give them something which could be potentially harmful. We've just got to wait and see what medications

they're actually on. Language is another barrier as well, especially in Bradford. We get a lot of Asian people, older Asian people don't speak English. So drug errors happen all the time really.

7.2.3.3 Interruptions and distractions

Interruptions were expected as a normal part of the working day. Nevertheless they were also seen as significant contributory factors. Furthermore, some were described as purely social (1SN, 17N, 20PT, 34P), which suggested that interruptions could also be independent of high workload. This nurse indicates the regularity of the problem but also how it can be worsened by ways of working:

'When you're making a report because an incident's happened, and when you look at the factors leading up to it, I think interruption, nine times out of ten is going to be there……you just can't concentrate on doing your medicines and nothing else until your medicines are finished…. the way we do our medicines on here, the way we work, we work in three teams. We've got four qualified nurses on a shift. The senior nurse will be in charge and then there'll be three trained nurses taking charge of nine or ten patients each. So there's three nurses crowding round one trolley, all trying to do their medicines at the same time' (6N)

The reality on the shop floor is that it's very rare you can do a drug round without being interrupted. If you're halfway through a complicated drug chart and you get disturbed, people go back and they don't always go back to the place they finished off and therefore one gets missed (23SN)

Somewhat surprisingly, what first appeared to be a social interruption emerged spontaneously through discussing with the first nurse participant the confusion that can result from drugs brought in from home by patients' relatives:

'But they do bring them in, and we ask them to, and make a note of it and we keep them in the drug room. I think another defence is you should have a tongue in your

head and you know how to say to somebody, just leave me alone while I do this, I'm doing some medicines, I'll talk to you about your tea-break later, it's one of them things where you're obviously working a medication out or you're doing your drugs, you've got the drug chart there and somebody comes in and starts chatting about Saturday night. Well, I'm always one to have a good natter about what I've done at the weekend, but you can imagine the management, well, why weren't you concentrating? Well, I was talking about my Saturday night out….'(1SN).

Further discussion prompted the participant to share how she dealt with what might be a dilemma for some practitioners:

'I mean I've more recently sort of turned round to people and stopped what I'm doing and actually said, yeah, it was really good, I'll come and talk to you about it in a little while, just let me do this. But not in a confrontational way. I think you can actually tell someone to bugger off and stop being a pain in the arse without saying, bugger off and stop being a pain in the arse' (1SN)

One of the pharmacy technicians raised the same issue and was very honest about being distracted for similar reasons;

'Interruptions as well are a big, big thing, not just for dispensing but for checking as well. And not just interruptions from the phone but also from your colleagues, who perhaps interrupt you with things that are to do with work but also interrupt you with things that perhaps aren't to do with work. And distractions as well, such as just other people talking and you're trying to earwig while you're doing something else' (20PT)

Others talked about their difficulty dealing with patient interruptions, and although intentions were good, the remarks suggested a degree of error naivety:

'Obviously you've got to be extremely tactful and appear that you're listening to them and then say, 'Right, well, I'll just do this for you,' and then do their medicines…they will interrupt you, but obviously if they do interrupt you, as long as

you tactfully say…. then they're OK the majority of the time' (18N)

'you come to do your drug round, your trolley's facing them, and they see that as an interaction for the day: 'Where have you been on holiday?' 'I haven't seen you for a while, how's your kids?' You know: 'Well, I'm here to give you medicines.' And then they'll start talking about something else and then they'll go back to something that's happened and then, because I know them, I have a lot that burst into tears because they need your time, and I'm not the sort of person that would say, 'I'll come back to you later,' because you can't in that instance. So then somebody else has to take over my medicine round' (24SN)

However, the nurse in interview 12 once again took exception to the dominant view of his peers that interruptions were inevitable when he boldly declared that:

'no matter whatever else, when you're on a ward round doing medications, and that is it. You don't get broken off for anything. If somebody asks you to do something else, you say, 'I'm just finishing my meds, then I'll be right with you.' (12N)

Interruptions were also described as problem in pharmacy where once again, different ways of working conspired with interruptions, to cultivate errors:

'the environment that we're often checking prescriptions in is often very chaotic with lots of interruptions and no time allocated as checking time. The time is mixed in with time dealing with the public, dealing with people coming to a desk in the middle of you checking a prescription, phones ringing, things going on behind you as well as in front of you, and that has become part of the way it happens here. And changing that system is difficult' (5P)

Indeed the public counter service seemed to be an added burden:

'certainly I'd say working in the dispensary, you end up with a situation very often where you've got irate patients waiting who create a fuss, which you're expected to handle, maybe breaks you away from doing something that you were perhaps

concentrating on. You're then expected to go back suddenly, all the adrenaline's vanished, and you're expected to calmly reflect on what you were doing a few minutes ago and pick up the pieces and hopefully ensure that your mindset is OK' (28P)

Nevertheless, from this apparent maelstrom, error wisdom was evident both in pharmacists' reflections of dispensary and, below, ward practice:

'I think medicines rounds are quite fraught and very difficult, and I'm encouraging some of our junior pharmacists to go on a ward round with a nurse just to see the sort of problems because you can't really help them until you can understand the problems that they're having and the constant interruptions, phones, and the more senior the staff, probably the more interruptions they get' (34P)

Another consultant highlighted the issue of *'prescribing on the fly'*, another way of working fuelled by best intentions, but one that didn't necessarily reduce the likelihood of error:

'And they'll [junior medical staff] try and do it very quickly and check the dose and scribble it in and we try to say, that's only OK if something is very, very routine. If there's a glycerine suppository that needs doing and the nurse wants to do it now, you can probably say you can write up a glycerine suppository. But if you're writing up stuff for infusion, really that should be done separately and you need to sit down and do it as an activity not as half of three activities all at the same time. So we've tried to limit the prescribing on the fly to try and make the prescribing step less interrupted. (10SD)

Ways of working to avoid interruptions were though perceived as difficult to implement and even counterproductive, as was the opinion of this SHO who had previously been a GP:

'I think that would be difficult. It would certainly be a radically different way of

working because most alterations occur either on the ward round or at short notice. It's not like in general practice where you can set time aside at the end of your morning surgery to do your repeat scripts or change your scripts. It would need a lot of thinking about and I would be concerned that errors might occur because doctors were not allowed to be interrupted. If it was the wrong time, then it might be that a prescription alteration was put off. For example, a nurse might ask if you could cross off a prescription which the senior doctor had said to stop and you haven't done it' (40D)

In summary, interruptions seemed to be embedded in the fabric of practice and one staff nurse phlegmatically pointed out that not accepting interruptions as an organisational 'norm' would be problematic:

'Your managers are one of the first who'll sit down and say, 'Right, we have to tackle these drug errors. Let's put tabards on to stop you being interrupted', but they're the first ones who are on the phone saying, 'Actually, no, can I speak to her now.'

(GA) Do you find that in any way frustrating? Don't let me stop you.

I was just thinking, I mean, it's not just your managers. Obviously you've got to think of all the other interruptions you get on the phone. Surgeons will phone, they always want to speak to the Sister. It's slightly different if you're a staff nurse, obviously. So they all want to speak to me and if I actually told them all, say, 'No, I'm on a medication round,' it's just—

(GA) Difficult?

Extremely difficult, yeah. It wouldn't happen. And also it would make my job a lot harder as well, in some respects, if I said, ' I'll ring you back,' to every single person I got a phone call from'(16N)

7.2.3.4 Knowledge deficits

This category was inclusive of the phenomenon of inexperience. Nurse participants were concerned about the knowledge base of some of their peers but also those who were newly qualified. They explained that a doctor's poor prescribing knowledge could lead to administration errors and implied that the nurse down the line often lacked the knowledge to prevent such an error. A senior nurse on an acute medical ward described an example which also illuminated her perspective on accountability:

'Experience, knowledge of drugs [is a factor]. Often you'll get people coming in on a multitude of analgesia and many - I think, often you'll get people on drugs that do the same thing, maybe two inhalers, like a Seretide and a Becloforte, the nurses just don't realise. And that to me, although it's prescribed, it is a drug administration error because you shouldn't be having both at once' (19SN)

Doctors shared the nurse's under-confidence about pre-registration training. Indeed three junior doctors could cite examples of their own knowledge deficits stemming directly from their training, one felt the pharmacological content lacked the practicalities of prescribing, and two didn't study pharmacology at all:

'Now, I don't know how many doctors you've spoken to of my ranking but in my medical school training, we didn't have pharmacology, they cut it out. It was a big thing that we were very upset about, at the end of the day you're fine to diagnose but if you don't know what treatments to give, what use are you? And it was an issue that was raised again and again but nothing really got done about it. By the end you kind of had a good feel for what drugs to use where but I'd never actually formally been examined' (29D)

The pharmacists who discussed knowledge deficits predominantly discussed those of their nursing and medical colleagues, yet again raising concerns about pre-

registration preparation but also alongside this, the difficulties of being new to an area and how other factors would ultimately precipitate the error:

'There are knowledge problems undoubtedly amongst nursing staff that are probably more acute in the general medicine areas than in the specialist areas. In the specialist areas people are dealing with smaller ranges and tend to be much more clued up about those things' (34P)

'The factors in this particular error that I would think contributed to it would be the fact that we've got brand new doctors who are not familiar with drugs in the same way as they will be in six months' time, somebody who was clerking a patient in later at night, and there were multiple drugs, and it's difficult at this point to know whether or not the person was broken off partway through doing that' (15P)

7.2.3.5 Faulty psychological processes

Rarely did the previously analysed incident reports hold any detail concerning the protagonists' psychological processes in a drug error. Some of these psychological processes were, however, discussed by several interview participants usually when narrating their own errors. It was also apparent that faulty psychological processes were implicated in lookalike/soundalike drug errors, and arithmetical errors. Importantly various thought-processing errors were actually laid bare in descriptions of double checking errors; here a pharmacist described a double capture error:

'… where you've got more than one problem on a prescription, your brain tends to focus on the first problem that you see and you miss the other one. I can think of one - a supply problem with an inhaler that had been prescribed and we went to a great deal of trouble to ensure that the patient got the treatment that she needed. There was another medication on the same prescription but the wrong dose, and we missed it. We dispensed it exactly as prescribed but the prescribed dose was wrong and because we'd focused all our attention into this supply problem, we

hadn't noticed the wrong dose, there were probably about three people involved in that prescription and none of us noticed the error' (2SP)

Two less senior nurses identified the inherent risks in carrying out the same tasks repeatedly, which appeared to contribute to skill-based automatic processing errors:

'Well, we check the control drugs and I think that people can become blasé about that, especially when you've got a patient that's on control drugs all the time, continuously on them, and you kind of get used to the dose. You know what dose they're on and you kind of know what it is before you've even looked at the drug chart' (3N)

And another concluded pragmatically that in a similar situation:

'I am not going to recheck that name band because I don't really need to because I do it by face'

(GA) 'it's part of human nature to take a shortcut?

'It is' (12N)

The phenomenon of expectation bias was described by a junior doctor:

'I think one of the problems is that people often get into the habit of a cursory glance, looking at a bottle, is it in date, is it not. Perhaps the most common thing that I'm involved with is giving some IV medication, but is it in date or not? And one always assumes that it will be in date, although actually that's not always the case and occasionally you do come across at the back of some cupboard something that's long past its expiry date. And it's very easy to look without really seeing' (26D)

The same problem is described below, but in the dispensary where routine tasks dominate, and staff handle hundreds of drugs per day, some of which are similar in

appearance:

I think from the drug point of view you've got the similar names, similar packaging, particularly where you've got generic brands. Quite often their packaging is all virtually identical.

(GA) The manufacturers?

Yeah. And people say, 'Oh, well, you should be reading the boxes.' But people don't, they see what they want to see, and if you see a box that is a particular colour and a particular style then you're expecting it to be a particular drug perhaps and your brain thinks: oh, yeah, that's what I want. (30PT)

Another member of the pharmacy department referred to the same phenomenon but explained how the perceptual confusion and expectation bias that leads to an error in the pharmacy department then results in a further, duplicate error in the ward setting:

'you get a patient who has been dispensed amlodipine and they've been prescribed amiloride, last week I got this error report, dispensed fosinopril and it should have been something else, another drug beginning with an F and ending with an L., I suspect half the errors by the nurses on the wards are due to mal-processing the information that is presented to them and I don't know whether you've seen these posters saying that it doesn't matter what order the letters in a word are as long as the first and last letters are correct, then you will be able to read that sentence' (33SP)

Finally, a junior doctor who was previously a nurse pointed out the risk of pattern matching:

'I think some of the nurses are very, very cautious, aren't they, so if they see a drug and they're not sure, things like digoxin…….sometimes the nurses think, oh, well, I won't give this, for whatever reason, so they just don't and they either leave a blank

or they draw a cross, and then that gets perpetuated from one day to the next day' (38D)

7.2.3.6 Inappropriate attitudes

Some participants claimed practitioners' attitudes were instrumental in contributing to errors. A junior doctor probably offered the most concise summary of the factor – *'it's a lack of care'* (29D); she continued in the very candid style she had throughout the interview, without hesitating to mention the way her work lacked due care:

'…..in some cases, you're presented with a patient's drugs. They come into hospital, they've just got a big box of them and [they say] 'Those are my medications.' But often I don't go through them and ask, 'Do you actually take this one five times a day, as stated on the box?' You just copy again on the labels. Somebody's prescribed it there and you just trust that that's it. (29D)

She did not, however, see inappropriate attitudes as isolated from other factors, adding that:

I guess that comes down to a lack of time. You really don't have time to sit down with a patient and go: 'This is your blue tablet. Do you really take this, this and this?' (29D)

Interestingly, just one pharmacist raised this as a factor and it was focussed on nurses' attitudes following a double checking error which resulted in administering penicillin to a penicillin-allergic patient:

'I think it's surprising that so many people were involved and that there was obviously a degree of complacency in staff attitude and a number of the nursing statements said, 'Well, I saw that it had been given several times already,' and that doesn't mean it's all right, does it? And that's basically not following the procedure, which is to check.' (34P)

An intensive care nurse took a similar view, concentrating on what she perceived as poor diligence, but again, in another discipline. She was expansive in response to the question: 'Are some errors more likely than others?' The response while suggestive of questionable attitudes was also reminiscent of another previously described factor –'communication deficits' where, poorly written prescriptions for example, could lead to errors but that inappropriate attitudes may be influential in the way a prescription is written:

Well, previously every day the medical staff would write for the 24 hours the drugs that a patient had to have on the big ICU drug chart and it irritated some of them because they had to rewrite some and they felt it was a bit of a waste of time, but there wasn't reams of it. So it was decided they would bring out pharmacy charts which would be pre-written and you would continue unless it was crossed out. And what happened was, just as they couldn't be bothered to rewrite all the stuff on the charts, they also couldn't be bothered to look through the pharmacy charts to see what needed crossing out and what was irrelevant (16SN)

A nurse from an apparently very busy medical ward questioned the vigilance of her nursing colleagues:

I don't know. I think to work in an acute medical environment, you've got to have a certain pace and I don't think many people have that. I think there are a couple of people on the ward that don't have the pace that everybody else has, and they don't look effectively enough. You always expect everybody to be as good as the best nurse on the ward, and it's difficult….you've got your prescription in front of you, it'll say prn 4 to 6 hourly, and people don't look at the maximum four times dose, and they won't look for that 4 times in the 24 hours (19SN).

Several nursing staff also pondered the attitude of senior colleagues and wondered whether their experience gave them a false sense of security:

'There's an awful lot of people around on the unit and I sometimes find it's the more experienced staff that are perhaps producing the errors because they've done it that many times before that perhaps the checks that they should be making are not there, whereas the more junior staff are a little bit more rigorous in what they do (13SN)'

The medical staff shared similar concerns about vigilance, but it was suggested that the 'type' of person was a key predisposing factor:

I suppose there are people which are a bit lackadaisical about everything and just kind of write things up. Someone thrusts the drug chart in front of them and says, 'Write them up for that,' and they sign it straightaway without checking anything. Yeah, I mean, that's kind of their personality. Every doctor's different, they've got their own skills, they've got their own good points and bad points (36D).

Broadening this idea, a senior consultant (7SD) suggested there was a particular problem in medicine with attitudes to protocols, which she raised prior to being asked about their effectiveness as a defence against error. Drawing on her own experience, she revealed that she was able to save time by taking a shortcut around some protocols and, underpinning this, she was inclined to think she was *'completely foolproof'.* When asked why she (and other doctors) might act in this way she felt that the historical lack of staff management in medicine meant that the consequences of non-adherence to protocols were less than in other disciplines, such as nursing. However, the notion of feeling fool-proof, and actually *expecting* to be, was occasionally expressed and in response to all sorts of different questions:

(GA) Having related that [error] to me, is there anything in particular that stands out for you in that incident?

Just the way I felt really because I'm the drug assessor so I shouldn't be making mistakes. I'm assessing other people every week and picking up on their mistakes

and it was the fact that I'd done everything apart from check to see that it hadn't already been given. (6N)

7.2.3.7 Double checking

Double checking medications is ostensibly a defence against errors. Yet here it was predominantly seen by participants as a contributory factor. It was raised in response to two open questions: Are you familiar with the idea of double checking? How can double- checking be helpful in reducing drug errors? Yet it was also raised spontaneously by several participants in their opening narratives. Four weaknesses were made apparent within the responses to questions which focussed on the checking process itself, and are shown in Table 8.7. Not all participants were critical of the process which accounts for less than 40 tabulated responses, and some participants discussed more than one weakness.

Table 7.7: Sub-categories within the category of double checking as a contributory factor

Sub categories	Doctors' comments	Nurses' comments	Pharmacists'/pharmacist technicians' comments	Totals
Deference to authority	4	4	1	9
Reduction of responsibility	1	7	2	10
Automatic processing	5	2	2 (with reference to nurses)	9
Lack of time	4	4	2	10
Totals	14	17	7	38

Deference to authority

The single response from a pharmacy practitioner which focussed on deference, although without certainty, concerned an occasion when a wrong vaccine was simply taken out of the fridge (BCG rather than Botulinum). She suggested deference could have predisposed to a lack of questioning:

'This technician was also training to be a pharmacist as well, so whether she assumed that this person [the qualified pharmacist] was right, I don't know. But it

never entered her head afterwards to think that it was strange for this particular drug - the BCG [vaccine] to be used for that purpose, we always do in a certain way and it had never been done like that, but she hadn't questioned it at all' (PT14)

A consultant was more explicit and certain about deference, which he believed could also encompass deference to those with a greater perceived arithmetical ability. He also alluded to the phenomenon of giving the 'answer' before the check:

'if your process of checking is one person follows the other's calculation, then they will just follow the error……and there can be hierarchy issues there. And I know sometimes I take complicated calculations to people and say, I've made up this calcium infusion. Can I just run it through with you? I've got 44 … here of 10% calcium and glucose in 15ml, that's 14 millimoles, 14 millimoles in 50, der der der, that's fine, isn't it? And they're kind of going, yeah, yeah, yeah, I think that that's OK … And that's not an independent check….they would defer to authority. And there's a speed of mental arithmetic hierarchy issue as well. The people who are quick with numbers will bamboozle those who are slower with numbers even if they're wrong, because people who are quick with numbers make mistakes as well (10SD)

A senior nurse from the same unit concurred with her consultant colleague using very graphic language and referring to a potentially fatal adverse drug event:

'some people can be quite influencing, can't they, and really: 'Well, this is what I see.' And the junior person believes at the end of it that they see it that way, or doesn't have the guts to stand up and say: 'Really, no, that's not what I see.' And to give another example, years ago now, a baby came back from a different hospital with a morphine infusion and a couple of the consultants checked the morphine infusion, put the morphine up and convinced a D grade staff nurse that the amount they were giving was what she said. And when she landed back on the unit and they worked out the baby was receiving five or six times the amount of

morphine than it should have been' (11N)

Reduction of responsibility

Some participants, especially the nurses, also believed that double checking diluted individual responsibility for the process. This junior doctor raised double checking spontaneously as she recounted some error defences, but then actively reflected on its reliability:

(GA): Anything else in the system that you think reduces the likelihood of errors?

Experienced medical staff, people that have been in the job a long time. Multiple people along the way checking things, though I suppose in a way it kind of takes away from your own responsibility. If you've got more people checking it, you could become a bit complacent: 'Well, I know it's going to be checked by two other people before it gets given,' or, 'It's been checked by two other people so it must be all right.' (29D)

Here an experienced surgical nurse is rather more assertive about the frailties of double checking also suggesting it may be counterproductive:

'it leads to complacency. Both people are expecting the other person to have checked it more thoroughly than them, in my experience.

GA: Is that, do you think, peculiar to nursing or is it something that perhaps you think might span the health professions?

No I think it's something that covers all health professionals.

GA: I wonder how that's emerged over time, any thoughts?

I don't know. Perhaps management have put the double-checking procedure there in an attempt to try and avoid or rectify errors. Perhaps they've based it on past experience, I don't know how it came about. But I think experienced professionals who've been involved in errors know that it's not a flawless procedure' (6N)

Furthermore, there was a suggestion that the inevitable social contact could promote an inappropriate informality which could further diminish responsibility and rigour:

'Well, I just think if you're the only person who's checking something and you know that you've not got anybody else to fall back on, you make sure that you check name, dose, date. You make sure that it's that medication for that patient and then you're going to check it again, and you'll probably check it two or three times on your own, whereas with somebody else you'll go: 'That's MST 30.' 'Yeah.' 'Right. Still in date?' 'Yeah.' 'Yeah, right. I'm putting one in the box, yeah. That leaves 44…OK.' And my personal opinion is it would be much safer if you were on your own because I think sometimes and especially if you're working with somebody you know as well: 'Oh, did you go to the pub last night? Did you have a good time?' 'Yeah.' 'Oh, there's 44.' (17SN)

Auto-processing

The double checking process was also described as being carried out with little active appraisal. Notably, there was cross professional criticism; the pharmacists felt their process to be more robust than that of the nurses largely because a first checker would not recite the medication details (or in arithmetical calculations, give the answer) to a second checker:

'You see nurses double-checking and they're standing together reading things out by rote really, saying – this is when they're going to give an infusion – 'This is the name, this batch number and the expiry, blah blah blah,' whereas for me, the way we work, you do it independently really without that second person there and it seems to set the cognitive processes running better to do it on your own. And I think they do that, nursing policy seems to be to do that together quite often, but that's not the way we would ever do anything' (34P)

In contrast, a senior nurse asserted that nurses *were* rigorous, although she would

be unlikely to have witnessed a two pharmacist check in comparison:

'I do believe that nurses are better at checking ampoules, at going through: this is the right drug, this is so many milligrams in this vial, and the expiry date, and I think that comes from just checking things like antibiotics. With doctors, they very often pick up a vial up and it's just: 'This is penicillin, 600mg. This is water.' (22SN)

A junior doctor, however, discussed the problem with reference to both doctors and nurses, and in a clinical setting where double checking was implemented for all medications. He also pointed out that checking blood seemed to command more respect:

'People just tend to have a quick glance at it and, 'Yeah.' And I think if you were to change one of the numbers, I think you'd find it quite startling how many people would just say, 'Yeah, that's fine.' Because what tends to happen is one person checks it if it's something familiar, flashes it in front of the other person's face and they say, 'Yeah, that's fine,' and then just sign it but they haven't actually checked everything over rigorously as they would do if it was like on a blood product (36D)

Lack of time

Lack of time to attend to checking (and indeed other defences) was a constantly recurring theme which contextualised the majority of participants' talk. This senior nurse was an obvious advocate of double checking but was not confident about its maintenance:

'It significantly reduces the risk. You're not going to eradicate it completely but it would significantly reduce the risk. There just ain't enough of us to do it, you'd need more qualified nurses' (23SN)

This lack of time demanded that double checking be selective:

'Again it depends on the staffing levels and time. Our normal drug round is just done by one trained. If a student's doing it, it's countersigned by a trained nurse. If

we're doing IV drugs, because we do specialist treatment – all the nurses are assessed as competent in giving that drug, so if they didn't feel confident, they would double-check it with another qualified nurse' (Int 24: Senior Nurse Dermatology)

The sub categories were also related; sometimes auto-processing appeared to be linked to reduction of responsibility:

'We do have a process where we think we should be getting stuff checked. And I'm certain there's an issue round the extent to which it just allows two people to make a common error rather than one person do it carefully and perhaps be more likely to get it right….I've heard that referred to as the Glanceman test. You find a man and he glances at it for you' (10SD)

7.2.4 Defences

Participants explicitly identified several forms of defence against drug errors. However, some staff (contradictory to others' expectations about being able to avoid error – see 'Inappropriate attitudes') suggested the inevitability of errors rendered all defences imperfect. Furthermore it was also apparent that a cache of further information on contributory factors and error orientation was emerging:

'I think that's a hard one because again there's always human error. But, like I say, there's the big chain and a lot of it is [poor] communication. If everybody knew what they should be doing, then I think we'd work a bit better. So if the doctor writes the prescription down clearly and properly so that we can order the drug and it's the right drug from pharmacy and then we check it appropriately, then there shouldn't be a problem in the chain. But human error, like I've said before, the doctor doesn't prescribe it or the doctor doesn't write it' (24SN)

In short, the defences were often the opposite of the contributory factors - knowledge was a defence as lack of knowledge was a contributory factor. A

notable human defence was that offered by pharmacists, especially when they were out of the pharmacy and in the clinical areas. Doctors were especially keen to extol the virtues of clinical pharmacists (1N, 10SD, 12N, 15P, 18N, 25D, 26D, 35D, 38D, 39D, 40D), as were some nurses (12N, 26D, 39D, 40D):

'Because you've got the pharmacist that checks all the drug charts every day, or should do, on the ward and you've got the nurses who, when they get more experience, know what level of medication can and cannot be given to a patient so, apart from the doctors themselves, I think all the bases are covered'(12N)

'But in terms of patient safety, the pharmacist is key. By and large, nursing staff will pick up on errors, I suppose the days when nurses just automatically think doctors are right are gone, but there are times when perhaps it's a fairly subtle mistake' (26D)

Acknowledging this, a pharmacist succinctly maintained that:
'we moderate the risks that they [doctors]take' (15P)

However, the pharmacists did not recognise other professional groups as being a defence against error.

The ability to think conceptually[1] was also evident among several doctors and pharmacy staff (10SD, 26D, 28P, 30PT, 34P, 36D); it also appeared to be an integral part of a systems perspective:

'having a good understanding of the sort of factors that lead to errors. I think it's important to see how other incidents have occurred because you can use those, can't you? You can definitely use that knowledge when you're checking. You don't just thrust something under someone's nose and say, 'Check this.' You've got to give them some space to be able to do it. Even if you are in a hurry, you've got to make the time to allow them to do it in their own way' (34P)

1 deconstructing a given situation into its key components and their relationships, using general rules

Here a consultant from the unit with the highest reporting rate in the trust discusses what he believed were robust thought processes:

(GA) You also recognise that outside of problems with environmental noise you could have a problem with illegible handwriting and you've stressed the importance of the clarity of the prescription sheets.

'Yeah, but it was also not just around them writing it carefully but actually thinking carefully, in a setting where they could get the protocol book out and check, 'vancomycin'. They weren't saying, that's 15mg … isn't it, yeah, that's right. But they actually had…..paused and thought, this is vancomycin and for this big baby. Is that the right sort of dose? Rather than trying to do it on the fly, so it just wasn't just about getting their script nice, it was about also the process of prescribing in terms of the brain bit as well as the handwriting bit' (10SD)

The nurses interviewed were less likely to cite their pharmacy colleagues as significant defences. Indeed less than half the sample of nurses identified specific defences, and *systems-based* defences were less likely to be cited. The importance of knowledge and experience was stressed by 6 nurses (1SN, 6N, 13SN, 17N, 19SN, 22SN) but three of them pointed out (after some probing) that junior staff were often more alert than their senior colleagues, showing some overlap between previous comments about inappropriate attitudes among seniors:

(GA) Do you think certain staff make errors more than others?

Yes.

(GA) Why is that?

I don't know. I wish I did.

(GA) But it happens?

It does. And again it seems to be senior staff whose names come forward or experienced staff, not always the F and G grades but people that have worked in

Neonates for many years and have got a lot of experience' (22SN)

System defences were cited most commonly by pharmacists and pharmacy technicians. Just one participant singled out the incident reporting system. Other system defences, mostly cited by pharmacists were:

- Appropriate training (19N, 7SD, 35D, 20P, 30P)
- Adequate staffing (19SN)
- Double checking (25D)
- Proceduralisation (20PT, 34P)
- Orderly storage (33P)

7.2.5 Reporting culture

Participants spoke effusively about reporting, a culture was illuminated and its consequences became perceptible. Other questions such as whether *all* drug errors should be viewed as rule or policy violations provoked responses that added to the picture. Among several nurses (1SN, 6N, 12N, 16SN, 22SN, 23SN, 27SN) – most of whom were senior and often dealt with the consequences of drug errors, feelings of guilt and blame were portrayed as unavoidable. This particular senior nurse although keen to accept the inevitability of errors and that the Trust was trying to move away from blame, argued that most of her nursing colleagues would still fear the outcome:

'Everybody makes mistakes. The difference is whether you're big enough to own up to yours and it's changing the culture. You don't know whether or not somebody's going to have an adverse reaction to what you've done. Having made a drug error myself, I know the pressure that you put yourself under, it takes a bigger person to own up to their mistake and do something about it, but it's letting staff know that that's OK and there isn't a blame culture. They're not going to blame you because you happen to be the person that administered this, but as a Trust we're going to look at all the steps that led up to you doing that and whether

or not there are things that we need to change…. still think we've got some way to go, and I think part of it is the way we report and that people think that if they put a drug error report in, somebody's going to come down from on high with a clipboard and summon them to their office.

(GA) So when a nurse fills in an incident report, is she unlikely to be thinking, I'll fill this in because a lot of people will learn from it, and more likely to be thinking, I'm filling this in, but I hope I'm going to be OK?

Most people are terrified. They think that they're going to be disciplined and that senior staff are talking about them, you've gone down in their estimation because you've made this drug error. (23SN)

Another nurse, previously identifiable by his alternative perspective asserted that the fall-out would not be confined to senior management:

'It depends on how willing you are to get a bit of a backlash from the management. If you're a senior D grade and you're looking for your next step up the ladder, putting in an incident form saying that whatever's happened, [you have]done this or done that or done the other, it can affect your chances and we are all aware of that' (12N)

Indeed there was an impression that if a nurse submitted a report s/he became part of a formal structure that would inescapably involve either some blame, guilt or a form of action inclined to warning rather then learning. As two critical care nurses succinctly suggested: *'nurses think they are going to get their wrists slapped'* (16SN), and *'they are aware of the upward trajectory of nurse action'* (22SN).

A junior doctor who had previously been a nurse recalled the recent experience of a nursing colleague following a drug error painted a similar picture:

'My background is nursing and so I tend to try and be as supportive of nurses as I can and I know that on this ward not ever so long ago, there was a drug error of some kind and a nurse got an absolute nightmare time for it, so I tend to be as

reassuring as possible, if there's not going to be any harm is going to come to the patient, then there's no point in making a big point of it and making nurses feel dreadful and causing problems' (38D)

However, the overpowering impression amongst nurses was of reporting being a thankless treadmill (3N, 12N, 18SN, 23SN, 24SN, 32SN):

(GA) One of your expectations, perhaps the most important – is feedback. But have you got any others?

No. I think that is the main one. I don't want people to think, well, I've sent that form in and it means nothing. I'm not going to do it next time. Because that's what will happen. It happened before with the big, long forms. People got fed up of doing it because it is a big thing and you've got to sit and concentrate and write everything down. And then I think, but also it's three pages and the one that goes to Risk Management on the bottom, you can't read, so it's a waste of time anyway. So the top two copies go to my manager with any of the extra sheets. The bottom one you can't read at all. So what they do with them, I just don't know. On the feedback form [you could have]: 'Right. We've followed this up,' or 'We've done this.' Just something' (24SN)

Or more succinctly:

'Another problem with the incident form, another downside is you put incident forms in but you never hear anything back either.

(GA) Feedback?

Yeah, it just goes into a black hole and, as far as we're concerned, why spend the time putting something into a black hole when you're not sure what becomes of it' (12N)

As has been discussed already, the reporting process was perceived as rather tortuous but it was doubly frustrating that even after a busy period of duty, such a form had to be completed, often against the clock:

'I mean, the only thing I could say differently is there isn't enough room a lot of the time to write and so you need to go and get a different incident, just write it on a different incident form. Because obviously that was the complaint about the big ones, because there was too much room and you were tempted to fill it all in and spend hours over it, where now, as far as I understand, you're supposed to fill in concisely and briefly what's happened, and then obviously write a lot more in the care plan and things like that' (18SN)

Whereas there was some dissonance in error orientation between nurses and doctors, there was much greater similarity in their views of reporting. Again the sense that reporting was a thankless task with little stimulation (9SD, 10SD, 21D, 26D, 35D, 38D, 39D), was plainly evident:

'I think if it was something serious or something potentially very serious could have come from it, and if something needs doing about it, then I'll be the first one to fill in an incident form. But I also think that just recording lots and lots of things, kind of for the sake of recording them, doesn't always lead to any particular action really' (38D)

As was apparent in the initial analysis, medical staff also generally eschewed the organisation-wide approach to reporting, preferring to share and resolve errors (apart from the most serious) locally (8SD, 21D, 26D, 35D, 36D, 38D):

The question of who does it, I think it usually falls to a member of the nursing team. I think doctors, I think we have quite a high threshold for what will actually decide, well, I feel strongly enough about this to fill out an incident form – which is probably, which is wrong, but I guess that comes down to how we value our time and how we use our time. I think most people would probably think that there is more to be gained by trying to make sure that the same thing doesn't happen again by verbally communicating with whoever was involved rather than filling out a form that goes to a third person so that a fourth person contacts the person involved and tells them

off about it. I think most of us would prefer to take the person aside and explain to them rather than spend 20 minutes filling in a form and then have no further input in making sure that the message was conveyed in an appropriate way. (26D)

This under-confidence in the system was for some, probably exacerbated by a sense that reporting was *'for settling scores'* (10SD) or a political tool – *'if you haven't got enough staff, put in an incident report and bombard management'* (8SD).

It was also apparent from the extract from Interview 26D (above) that nursing staff may be taking an overarching responsibility for reporting.

The barriers to doctors reporting, for the juniors in particular, were to avoid losing face and provoking ill feeling (9SD, 25D, 29D, 35D, 40D):

'If I'd discovered my own error, I'm just not that honest. I'd just probably cover myself up. I've never done an incident form before. You look to your senior colleagues for that kind of advice and if you're reporting them, you feel: gosh, can I?'

(GA) 'So there's a bit of reluctance here'

'Yeah'

(GA) 'Do you think there's a general feeling of reluctance among junior medical staff, maybe some caution here?'

'Yes, definitely. I guess you don't want to land your colleagues in it, although I know the whole point of it is to learn from your mistakes' (29D)

The grind of reporting was also evident in the pharmacists' responses (2SP, 5P, 14PT, 15P, 34P) underpinned by a feeling of distrust (4P, 5P,14PT, 20PT, 28P, 33SP, 34P) in the organisation-wide system, a distrust which perhaps shored up their belief in the regional reporting scheme to which they also subscribed. A

similar sense of collegiality to that of the doctors percolated through, although the ward-based pharmacists were especially concerned about reporting errors made by their doctor colleagues (5P, 15P 28P, 33SP, 34P). They were however generally united in their opinion that it would be impossible to report *all* drug errors and that a reporting scheme that significantly increased reporting would also present another problem – how would the organisation handle that much data and address the persistent issue of poor feedback?

The most senior pharmacist in the sample provided a pithy response when asked about the existing system:

'From a pharmacy point of view, the weakness with the form is that it doesn't supply the person who's investigating the error with enough information to take that forward. The perception of all the staff, not just my perception, is that the actual process of having to complete a form, even though it's so short, to some staff, in itself, interferes with their day to day work. The actual process of getting the information you need even to fill that form in a busy dispensary is irksome' (02SP)

The same criticism was evident in the comments below. The participant proceeded to describe loyalty to others and the consequences for them as disincentives in reporting. This pharmacist like some of the doctors, also preferred a very local resolution:

'You're quite conscious of the fact sometimes: well, this is actually going to be too much of a hassle to bother to report it; I'm not going to. And then, of course, you then find something that perhaps you feel, well, this ought to be reported. And then in the back of your mind you're conscious of the fact that, well, hang on, five minutes ago, I made a decision not to report another error. Am I showing undue favouritism to one member of staff and showing undue unkindness, if you like, for want of a better word, to another of my colleagues? But, I mean, obviously in the situation where you're talking about a different profession and you do worry that

you are going to get a colleague into very deep trouble over something that they've done as an error which is potentially dangerous to the patient, but maybe a quiet word in their ear is sometimes the appropriate way forward to try and make sure that they are learning from the error and hopefully taking that on board without it becoming a formal disciplinary type process that sometimes these things will evolve into it' (28P)

Similar thoughts were expressed by another pharmacist although far more emotively:

(GA) Obviously there are several weaknesses [in the reporting system] as far as you're concerned?

'All right. We had another - just imagine a patient perhaps suffering incredible damage from a mistake done by a nurse. That nurse makes another error two weeks later. The pharmacist comes to me saying, 'I'm not going to report this. It's going to finish her off. Trust policy is that they're going to institute disciplinary procedures on a second error. I can't face the trauma of having ruined this nurse's life. I can't deal with this.' That's a weakness of our error system. Imagine a consultant prescribing something that has caused incredible damage to a patient and the consultant knows that this is the case and two weeks later they prescribe perhaps exactly the same situation and then six months later they do exactly the same thing. Would you report him? Would you wreck somebody's life? I don't know' (33SP)

Finally, an experienced pharmacist eloquently spelled out the risks of erring, aggravated, she claimed, by societal pressures:

'I was reflecting before the interview on what my perception was of how things have changed. I've been a pharmacist for a long time and obviously things have got busier, but I think one of the biggest changes is a move from a culture of no blame and understanding in the issue of a serious mistake, because I mean I can

remember, thank God, not that I've been involved in anything, but I can remember some serious errors occurring which involved patient deaths when I was a much younger pharmacist, and how that was dealt with to how things are dealt with now. And although I know what the Trust says about a no blame culture, we're not living in an environment in our society any more where that is possible, and people point fingers. They do blame. There are massive consequences, consequences almost beyond what they should be, if a mistake does happen and I think people are quite fearful. I mean, I've had a friend who's a nurse who's been struck off for an error involving a medication' (4P)

7.2.6 Inter-professional dynamics

As can be seen from the text so far, there were some tensions and sympathies between professionals. These emerged largely from the responses to the question – 'do you think error reporting is perceived differently by different professional groups?' Nurses appeared to be caught in a bind which seemed peculiar to their own discipline. Following an error (whether they had reported it or someone else had), they, rather than any associated systems factors, seemed to become the subject of scrutiny. The impression was that this sometimes culminated in blame without obvious justification, and some self-deprecation. This contrasted with the medical staff who did not show the same level of self-deprecation, but agreed that the nurses seemed to bear the brunt of any action against individuals. Some pharmacists concurred with this yet unlike the doctors they appeared rather intolerant of certain nursing behaviours and practices.

Some nurses (12N, 19SN, 22SN, 24SN, 32SN), including the often outspoken and divergent participant below seemed to think that doctors held an unswerving loyalty to their colleagues following an error, and compared with nurses demonstrated much more mutual support:

'Nurses see a drug error sometimes and they'll walk away from their fellow colleagues, whereas doctors see a drug error and they'll stand behind each other

till the hilt, defending that drug error. I've never seen a major, major incident myself personally but I witnessed the fall-out from a major incident and basically all the nurses stood against one another, saying it wasn't their fault, where all the doctors stood behind the person that did it and supported everybody that was involved. So I think drug errors are seen completely differently by different professions. Doctors are more, it doesn't matter, it's under the carpet if they've made the mistake, where nurses are more willing to rat out each other' (12N)

The perceived lack of collegiality in nursing didn't seem to prevent nurses reporting compared to doctors. This was borne out by two senior nurses (13N, 19N) who categorically claimed that if an error occurred, the medical staff would expect the nurse to complete the report – a situation that was actually confirmed by some of the doctors (25D, 35D, 39D). One advanced his reasoning for this below (39D), if the nurse gives the wrong drug – even if the nurse may have acted on a wrong prescription, the responsibility lay with the nurse. He also however, veered back to the medical inclination to keep any process local and informal:

(GA) Would you feel comfortable for a nurse to fill in a report about your mistake, or would it be better if you did it?

I'd expect them to fill one in, to be honest.

(GA) You wouldn't be threatened by that?

No, because they're the ones that might have picked it up and they've given it so they feel they have to fill in a report because they've actually given the wrong thing. So it would be them and I wouldn't mind. I'd expect that really.

(GA) OK, pragmatic about that. Do you think you should fill in another form then, to explain your perspective on the events or is that ever going to be useful in your view?

It wouldn't be useful. [Although] I can see that we probably should fill it in.

(GA) Why do you say 'we probably should'?

Just to document what happened.

(GA) Like case notes?

Yeah. If anything came of it, then you'd need to remember what you've done and why you've done it. But in terms of usefulness, it's more useful for someone to sit you down and say, 'Why did you do that? This is what this does, so don't do it again.' (39D)

A lengthy behavioural analysis was provided by another junior doctor which included his thoughts on nurses' motivations to report but added that nurses usually inherited blame:

'Most doctors' opinion is that nurses love them. They always have them in their back pocket and take it out [for] any kind of thing that goes on… that's the general comment. We don't tend to fill incident reports out. I don't know why. Doctors…..tend to just get on with it, whereas I think the nurses from the protocol system, the way they're educated is that if something happens, something needs to be done about it, and everyone needs to know about it'

(GA) 'But doctors do document events?'

'Yeah. I think, in fact, I know that the main reason is the nurses feel that they will lose their job. You say, 'Why are you filling that in?' and they say, 'Well, because I'll lose my job and you'll just get a smacked hand.' I think they feel that if something goes wrong, they're covered. It's the consultant that gets the blame but it's all swept under the rug, whereas the fall guy if you want is the nurse' (36D)

It is interesting to compare the above cynicism with the nurse below who while recognising the limitations of reporting also recognised her responsibility:

'And, having sent in incident reports on some subjects for many moons now and seeing that, in fact, little is done about it to my observation, then that's how I feel. But I would always fill them in because we're required to and because I will admit that there is a percentage where it's useful' 16SN

However, while a reliance on nursing staff and disinclination to write reports may not reflect the ideal learning ethos among medical staff, the doctors had a generally unconditional respect for nurses' reporting habits and appeared aggrieved that they seemed to be frequently receive blame (7SD, 10SD, 26D, 29D, 35D, 36D, 38D),

Several nurses admitted that they wanted to be treated like any other group of staff, shoring up the concerns exhibited by their doctor peers who felt they were more likely to be blamed as a consequence of reporting an error. Most clearly recognised that prescribing errors translated into administration errors and that meant that the root cause was missing, but here it's recognised by a junior doctor:

'My name was on the critical incident report, but nobody came back to me and said: '[Name], would you like some training in prescribing drugs?' I was asked in the end, several days later, to write a quick statement of what I had done but that was what we thought would be the best thing to do. Nobody had asked me to do it. It was the sister who was writing the form that thought, 'Maybe you should say your point.' And I felt the nurses were getting into far more trouble than I was because they were the one that gave the drug and they would never have given it if I hadn't written it on the form. And I think that is really upsetting for a lot of nurses and it upsets me that doctors rarely get struck off or even talked to about an error whereas the nurses, they just get all sorts of trouble for it. I think it's unfair and I'm not quite sure why. It's apparently, you know, when I speak to senior sisters, it's always been that way: doctors make a mistake, the nurses pay for it. So, no, I think I should have written a critical incident report about myself, but I didn't, I just wrote a statement to go with the nurse's one' (35D)

Some of the pharmacists offered virtually the same opinions on the reporting behaviours of doctors and nurses. Here a senior pharmacy technician has not considered reporting as part of a doctor's role (or responsibility) which perhaps adds another layer of insight into the culture:

I don't think I've ever seen an incident report filled in by a doctor that's come through to any of the departments I've worked in actually. I've never thought about that before. Yeah, it does tend to be nursing staff who fill in the forms but maybe they're the best people to do it anyhow.

(GA) Why might they be the best people to do that?

I shouldn't have said that, should I? Well, I suppose, the time factor possibly, although … like on the wards, and the fact that they're involved in every aspect of the ward as well gives them better oversight of what's going on.

(GA) Big picture. Doctors less so?

Yeah. Especially when they've got to whizz round different wards. The nurses are stuck on one ward and know the patients. (20PT)

Alternative views were also provided by the pharmacists, in that they felt nursing as a body was sometimes the cause of their own blaming behaviours:

'Nurses are much more critical of themselves if they transgress, even if that transgression doesn't necessarily result in a problem, simply because somebody has not done something by the book' (15P)

Others seemed to have grown tired of nurses' inability to understand the role of pharmacists and the pressures in pharmacy:

'I sometimes wonder if there's an element of 'blame pharmacy' kind of thing, from the medicine side of it'

'(GA) You're not the first person to say that. Just a bit of antagonism there, maybe?'

'Yeah. 'Oh, pharmacy are slow and always doing things wrong,' or whatever. I mean there's probably all sorts of things from the pharmacy point of view that we could fill in the risk incident about but don't. I mean, obviously in terms of the drug

errors, they always get filled in. If there's one gets found, then it gets filled in but I do think that the wards will probably fill them in unnecessarily sometimes. It's like, 'Oh, pharmacy!' (30PT)

'Out of every 100 drugs ordered by nurses, how many errors do we get? 40%, which is horrendous. Maybe the hospital number's missing, maybe there's no dose, maybe the dose should be bigger. But if you analyse it in how well are these filled in, 40% error rate, and we dispense from these….and yet the nurses give us hell saying: 'Why can't you dispense it?' 'Because we haven't had the prescription down.' And so they say, 'Well, the doctor needs it for a ward round. Can't you dispense it without a prescription?' Would you? No, you wouldn't' (33P)

7.3 Co-rater's perspective

As was explained in the previous chapter, the raw data from 6 transcripts were shared with another doctoral student who was a psychologist concurrently studying organisational factors in drug errors using human error theory. It is not the intention to provide a detailed review of the co-rater's analysis here but to give a summary of her main conclusions. The implications of her involvement will be revisited in Chapter 11. Although there was considerable common ground in her identification and categorisation of contributory factors there were some notable differences:

- Interruptions and incorrect checking were described as subcategories of faulty cognitive processes
- Lack of experience or knowledge deficits were contextualised as problems with 'standard operating procedures' and poor policy dissemination
- Standardisation was judged to be a contributory factor – precipitating automatic processing by practitioners
- The co-rater's terminology was sometimes different [e.g. standard operating procedures]

In relation to the other categories there was further common ground between our

attribution of phenomena to named categories. However, the co-rating led to a discussion of the difficulty in separating reporting process from reporting culture, and she also added that the category of inter-professional dynamics was illustrative of the reporting culture. Finally she also extracted different quotations to illustrate key concepts.

7.4 Conclusion

The initial or primary analysis produced a framework of findings with which to construct an enhanced reporting system - specifically for drug errors - as suggested by the interview participants. There was some common ground between the findings from Stages 1 and 2, for example, it was apparent from the incident reporting analysis and the interviews that individual blame was sometimes evident in nurse-authored reports without any obvious justification. Although a finding such as this, from the report data, cannot literally be validated by the interview data, but there is a corroborative potential as suggested previously.

The participants held clear views on the structure of an enhanced reporting scheme which can be summarised:

1. Terminology should be clear and promote understanding
2. The process should be clear but allow sufficient detail to allow analysis
3. Tick boxes would facilitate achievement of the above as would a dedicated scheme for drug errors
4. Free text spaces should be maintained
5. The reporter should offer comment on causation
6. Local action could restore some sort of feedback
7. Structured support for reporters in both the process and outcome of reporting is essential and may reduce any perceptions of blame as well as encouraging learning

The participants also exhibited considerable knowledge of error causation,

concatenation featuring strongly in their narratives, [e.g. inappropriate attitudes may be linked to high workload which can lead to communication deficits]. A list of contributory factors was constructed and although communication was a common factor as it was in the incident report analysis, high workload and interruptions were far more prominent here. Interestingly, a low workload was also seen as precipitating error and interruptions were sometimes purely social. The time and confidential space to talk freely about errors and their reporting surfaced strong concerns about the experience and impact of faulty cognitive processes, as well as illuminating what were clearly perceived as problematic attitudes. A strong critique of double checking emerged – used by all three groups as a means of defending against errors but viewed as a contributory factor.

The process and consequences of reporting were sometimes detrimental to the notion of reporting as an opportunity for learning. Although reporters recognised reporting could potentially identify errors and their causes, concerns about action taken and feedback predominated over learning; the inter-professional tensions and differences were additional complications. Nurses felt doctors clearly made prescription errors but these were rarely a part of the reporting scheme, pharmacists were dismayed at nurses' ways of working, and doctors freely admitted they either knew little about reporting or were uncomfortable about the process and its utility – sometimes feeling reporting was not their domain. However, all professions were united in advancing the belief that nurses were unfairly treated *as a result of* reporting.

Reporting was perceived as a thankless treadmill. An exception was the staff in the neonatal unit. Through their comments, and across the disciplines, they appeared open about their errors, confident about their openness – especially within the unit – and pragmatic yet supportive in any action taken.

CHAPTER 8: METHOD FOR THE DESIGN AND PILOTING OF THE ENHANCED REPORTING SCHEME

8.1 Introduction

This chapter describes the methods employed in the design and subsequent mini-piloting of the enhanced reporting scheme. The term mini-pilot is used to reflect the small scale, short term of the piloting process. The design was informed by the combined data from the incident report analysis and the interviews, together with specific aspects of the relevant literature on drug/medication errors and incident reporting. It was apparent from an early stage in the interviews that the enhanced scheme would require a different template to the existing, generic, incident reporting scheme. This, together with the majority of interview participants having suggested drug error reporting required a separate scheme, led to the enhanced report template being solely for drug errors.

To gain increased detail, promote recall, yet also increase ease of completion, and in line with both the reviewed literature and the empirical findings, the format would include a series of structured prompts and tick box options but also space for free text. It was envisaged that the scheme would increase learning at the point of reporting. This would firstly be achieved through providing clear definitions of key terms. Secondly, accompanying guidance would highlight the cognitive processes that might contribute to a drug error, as well as the importance of system factors. A list of contributory factors, drawn from the stage 1 and 2 data, and further informed by the literature, would be included that could be identified and ranked in terms of importance, but primarily by the reporter rather than their manager. This format was also designed to advantage the manager as well as the reporter. The literature on medical error reporting demonstrates that blame is not an uncommon barrier to reporting (Wakefield et al 1999b, Uribe et al 2001, Kingston, 2004,

Woolever 2004, Waring 2005). The spectre of apparently inappropriate blame was also evident both from the incident report analysis and the subsequent interviews; it was believed that if the above changes increased the objectivity in reporting, it might also reduce the inclination for inappropriate blame. Finally, the reporter (and manager) would be warned of the risk of hindsight bias in considering causation.

The design of the mini-pilot is described before presenting the specific rationales for each part of the pilot format (Materials and Measures). The quantitative and qualitative methods employed in data analysis are also described.

8.2 Sample

The pilot sites listed in table 8.1 were not randomly selected. Their selection was nevertheless reasoned. It was judged important to provide a diversity of clinical context, with a spread of patient age groups, clinical specialism, and types of care. It was also decided to include a unit – known for its inclination to report and with a proven high reporting rate, and a unit where the reporting rate was comparatively low. It was evident from a study of railway driver's' inclinations to report incidents that reporting rates differed by area and that this was probably indicative of different subcultures and related safety climates (Clarke 1998). This together with the empirical data from this study suggested it might be worthwhile considering differences in the nature and content of incidents reported across the pilot sites.

In fact examination of the reporting rates over the study period 1999-2003 easily demarcated a zealot unit – the neonatal unit, which had the highest reporting rate across all specialist units in the trust in the study period 1999-2003. Another individual specialist unit – the Oncology ward although having a lower, relative reporting rate had, following interviews with 3 of their staff, showed a marked interest in the study and requested to be part of the mini-pilot scheme.

The surgical and elderly wards had a much lower reporting rate, in contrast to the Neonatal Unit; however, both pairs of wards were also included to allow

representation of the two mainstream clinical specialities in the trust: medicine and surgery. The reporting rates from 1999-2003, are shown in table 9.1 alongside rates of admission and 'transfers in' as surrogate markers of patient activity. From the four specialities then, there was only one volunteer unit (Oncology). In order to include dispensing errors in the mini-pilot scheme, all reported errors concerning drugs supplied to the pilot sites were also included in the study. However, data were not available on the dispensary's previous reporting rates.

Table 8.1: Pilot sites - reporting rates and admission rates

Pilot site/clinical location	**Reporting rates 1999-2003**	**Admissions to the ward/unit and transfers in or consultant changes 1999-2003**
Neonatal Unit	116	2,833
Oncology Ward	23	18,893
Surgery (2 wards)	43	14,242
Elderly medicine (2 wards)	30	15,991

8.3 Access and recruitment

The non-volunteer locations were initially approached by email, and then by telephone contact with the speciality managers and clinical governance leads. In relation to the surgical and elderly wards, the respective managers identified the participating wards from the range of wards available within the divisions. A written summary was sent to the unit managers concerned (and ward managers, where applicable) explaining the development and process of the mini-pilot (See appendix item 16), with a copy of the enhanced report attached. Informal discussions with the Local Research Ethics Committee led to the mini-pilot being classified as a quality improvement initiative and as such not requiring ethical approval. The Ethics Committee were nevertheless informed in writing of the mini-pilot scheme (See appendix item 17 for the letter).

8.4 Materials and measures

8.4.1 Sources of materials and measures

The materials and measures required to collect and analyse the data for this stage of the study were the report form and the accompanying guidance on administration, completion and return. The enhanced report form and guidance are available as appendix item 18.

A number of sources of information were influential in the design of the enhanced report:

- The data extraction tool for stage 1
- The data from Stage 1
- The data from Stage 2
- The literature reviewed
- Feedback from Trust committees and significant individuals involved in drug error reporting
- Trust IT specialists
- Trust Medical Illustrations Department (who modified the layout of the report form to meet the Trust house style)
- Legal requirements (set by the Trust solicitors)
- National Patient Safety Agency perspective

8.4.2 General considerations in design

The incident report analysis demonstrated a lack of specific detail concerning drug error as it was drawn from a generic system. The interview data showed that a clear majority of participants wanted a separate form. Moreover, drug errors remain a significant problem. They were the second most common type of incident reported to the NRLS between January 2005 and June 2006 (NPSA 2007a). It has also been demonstrated that the ratio of drug errors to preventable adverse drug events is high (Bates et al 1995b). Consequently a scheme was designed that was

specific to drug errors. To retain the specificity of the proposed scheme, definitions of drug errors, near misses and adverse events were included in the guidance to reporters, which would also have the added benefit of increasing the validity and consistency of the pilot data and any subsequent analysis (Kane-Gill & Devlin 2006).

It was also thought necessary to provide explicit guidance to clarify the importance of systematically describing causation, which is supported by Johnson & Holloway's paper on the regular over-emphasis of the human contribution in aviation accidents, their point strengthened through citing Ayeko:

'it is my belief that when we [simply] seek 'cause rather than *information about* cause during accident investigation, the direction of the investigation often veers towards elements that are more likely to be linked to blame than the mitigation of risks' (Ayeko 2002, In Johnson and Holloway 2003, p5)

The overall format of the report guidance was designed to provide a logical and simple flow of information to the reporter, and the report form proper was designed to receive such a flow of information from the reporter, stimulated by structured cues in understandable language. Free text can provide valuable contextual information that allows explanation of the incident in question (Runciman, 1993), but the shortcomings of free text are sometimes ignored. Kaplan and Fastman (2003) have alluded to the need for check boxes *with* a narrative to 'enhance analysis' (p69). Mindful of comments such as these and the empirical findings here, a blend of free text and cues was adopted.

Tangential to this was the creation of an evidence-based list of contributory factors - perhaps the most radical departure from the traditional report form. There were several rationales. Although the traditional report form bore a dedicated free text box titled '*Underlying Causes*', the incident report analysis showed it often contained data characterised by brevity, focussed solely on the protagonist's

actions, and in some cases lacking any indication of cause. Furthermore, the interview data demonstrated a strong willingness to consider tick boxes for the most common contributory factors. Finally, it is well documented that a higher cognitive burden is carried in free recall than recognition, and there is little time to complete reports. The way in which these factors were to be ordered nevertheless created a dilemma.

As previously discussed and illustrated in the background review, the predominant model used to analyse error is underpinned by the concept of multi-factorial causation (or concatenation), and differing levels of factors. Differing levels of factors can be organised into: unsafe acts, environmental (or error producing) factors, and latent conditions (Rasmussen 1982, Reason 1997). A very relevant example of this approach was Busse & Wright (2000), who developed an intensive care (ICU), incident reporting scheme in a format which separated multiple factors into organisational or error producing factors, and individual factors. They described these as distal and proximal factors respectively. This demanded that staff chose from a predetermined list of highly specific factors pertinent to ICU practice [e.g. 'endo-tracheal tube not properly secured']. The 10 'proximal causes' classified in this way were, however, error types rather then actual causes, excepting the rather vague term of 'thoughtlessness'. The distal factors were clearly factors rather than types but the terminology sometimes lacked specificity [e.g. 'night time' – which would require additional detail to unpack its meaning]. 'Agency Nurse' was understandably listed as a distal factor, but reporters may interpret this as either an individual factor or active failure on behalf of the agency nurse, or a latent factor [i.e. the inappropriate hiring of agency nurses by management instead of recruiting permanent staff]. Moreover, the terminology of proximal and distal, whilst familiar to medical staff, could prove difficult to use as mutually exclusive headings.

It was consequently decided, primarily to ensure ease of understanding, to employ

a single, undivided list of error producing and systems factors in alphabetical order. This would be based on the clinician's language evident in the Stage 1 and 2 data, and guided by the terminology of the NCCMERP taxonomy. Most of the orthodox human factors terminology was avoided [e.g. skill based, performance error] as it was judged to be potentially off putting to reporters, who would likely be unfamiliar with human error theory. Information on unsafe acts had been almost completely absent from the Stage 1 data, but was clearly evident from the interviews. Thus it was decided that the report guidance would explicitly encourage the reporter to provide details on the circumstances of the error, *including* asking them to consider their thought processes at the time of the error.

In line with Dekker's perspective on error genesis (Dekker 2006) - a range of causative factors is often apparent but tend to be jointly sufficient - it was also decided to give reporters the opportunity to rate the importance of multiple factors. This was seen as an efficient and cost effective way of re-enfranchising reporters through giving them the opportunity to describe causation in more detail. A metric scale of 1-10 was included adjacent to each factor thought, by virtue of its familiarity, to be the most accessible range of numbers. Furthermore, Oppenheim (1992, p235), has suggested a factor analysis is possible with just 10 factors. This type of scale does, however, harbour methodological complications. These are listed in table 8.2 below and suggested remedies are also offered.

The format here was also designed to allow the manager to retrieve information easily and then add their own comments, again prompted by structured cues which included a focus on action taken, and a free text box which asked for a summary of preventative measures. A key attribute of the proposed reporting system was then, to paraphrase Kaplan & Barach (2002), to engage all staff in safety activities.

Table 8.2: Methodological complications of metric scale and suggested remedies

Complication	Suggested Remedy
Inter-rater reliability can be poor (Oppenheim 1992)	Not usually applicable: in most reports only one person will rate the importance of a factor for each reported error
Reporters will refer to an arbitrary set of numerical values on an ordinal scale. Extreme values require a reference (Oppenheim 1992)	Guidance must be explicit: 'Identify which factors and rate importance' 1 is marked as least important and 10 as most important
Some factors may generate a halo effect. Reporters who are critical of the organisation may use the scale to vent their frustrations; others taking the opposite view may be unrealistically accepting (Reason 1997)	Training to identify this as a potential bias. Gather as much data as possible to create an average (Reason 1997)
Reporters may be disinclined to use extremes (error of central tendency) (Oppenheim 1992)	Training to identify this as a potential bias

8.4.3 Specific considerations

The rationales for each section of the report form are given in appendix item 19, followed by the rationale for the content of the guidance in appendix item 20. Both items show, where applicable, the source of the underpinning rationale. The rationales are:

- Organisational imperative – to meet the reporting criteria set by the Trust, its solicitors, or the Clinical Negligence Scheme for Trusts
- Stage 1 findings
- Stage 2 findings
- Literature/systematic review findings

These rationales are essential in that they collectively form a discrete and objective evidence-base for the structure and process of the enhanced reporting scheme. For example, the inclusion of a contributory factors list and scoring scale met the trust requirement of addressing causation, yet the documentary analysis demonstrated that the existing system of a free text box alone did not provide sufficient information. Additionally the majority of interview participants held that a

tick box option of common factors should be included and 50% of the participants suggested the reporter should have a direct role in attributing causation. Finally, the reviewed literature showed that robust reporting demands factor identification, causation is very likely to be multi-factorial at various levels, and the reporter should describe causation.

8.5 Procedure

8.5.1 Length of mini-pilot

The mini-pilot was three months in duration, a time frame agreed with senior and trust management, in conjunction with the study supervisors, to allow sufficiently rapid analysis for prompt feedback to the wards/units involved, and complete all data collection and analysis activities within the scheduled three year time frame.

8.5.2 Staff training

Following formal presentations to the Trust's Clinical Risk Management Leads, Medical Director, Chief Nurse, and Director of Pharmacy, as many staff as possible within each participating clinical unit/ward were trained by the researcher to use the scheme. This took approximately 6 weeks and was immediately prior to the commencement of the mini-pilot. It was a systematic, and notably intensive process where as many staff as possible were instructed on error, causation and reporting, mostly in small groups. Firstly, each speciality's clinical governance meeting preceding the mini-pilot scheme was attended by the researcher and the scheme explained. The related unit management meeting, nearest to the date of the clinical governance meeting, was also attended and again the scheme was explained. Non-management grades (the remaining clinical staff) were then seen in their clinical bases. Pharmacists had predominantly used a separate 'pharmacy only' regional system for reporting drug errors. However, a commitment was made by pharmacists and pharmacy management to use the enhanced form for all drug errors they detected during the pilot. Pharmacists and pharmacy technicians were

seen at their lunchtime departmental meetings.

Staff were given a blank enhanced report form which was explained section by section, with the guidance explained simultaneously. The submission process, which was made as similar to the existing mechanism as possible, was reiterated. It was impossible to see every member of staff at dedicated meetings, so the researcher also visited the units/wards on an ad hoc basis and spoke with individuals at their convenience (this proved to be very useful for feedback on design).

Brief written instructions on the submission process were also left on the ward in the clinical areas and in rest or meeting rooms (See appendix items 21, 22, 23). The actual layout of the report form – 50 carbonated forms in triplicate were presented in an A3 size covered ledger with guidance printed on the adjacent, inside cover - aimed to ensure that all staff would have access to guidance on completion and submission. The scheme was also discussed in detail with the Trust Risk Management Department so the submission process could wherever possible mimic other existing reporting processes, i.e. their administrative staff could still code the data effectively for audit requirements, all those who required copies would still receive them. It was also agreed with the NPSA that the enhanced report would replace the existing scheme, avoiding the irritant of staff reporting twice. The unit-based group training sessions inevitably led to questions, which often served to improve the training process.

8.5.3 Training issues

A common question was how to report 'someone else's error', a question which also illuminated some of the underlying tensions between professions. Accordingly, participants in the mini-pilot, if they were the reporter (or the person who had found the error) but not the protagonist, were asked to make contact with the protagonist so they could submit the report. The rationale being that the

protagonist would be more able to identify the contributory factors concerned, especially any cognitive processes. If this was not possible, the less favourable option of the reporter submitting the report was proposed. It was added that reporters should not feel obliged to name the protagonist. This approach was informed by a previous study on barriers to reporting (Uribe et al 2002) where the notion of telling on someone else was the third most likely barrier.

Another common question across the disciplines was whether each and every drug error seen should be reported. It may be both 'idealistic and impractical' to report all medical errors (Uribe et al 2002, p277). Providing an affirmative answer seemed inappropriate and dismissive of the demands of practice. Consequently, reporters were then asked to be discerning in their reporting, considering the outcome of the error, but also any learning potential. Near misses that could have easily led to an adverse event or were more likely to recur were also described as highly relevant (Nebeker et al 2004). It was also emphasised that from a research perspective, a valid evaluation of the new format rested on capturing what Nebeker et al have called a 'meaningful report' (p800) – one that includes competing and contributing factors.

8.6 Analysis

The report form allowed the identification and/or measurement of several variables, each of which corresponded with the 13 numbered sections in the enhanced report form. The qualitative and quantitative data were analysed using a range of methods. Where possible the data was analysed using the methods employed in Stage 1 [e.g. error reporting rate], but also the subsequent findings [e.g. evidence of inherited blame]. Other methods were introduced where new variables were evident. Table 8.3 shows the individual variables, in accordance with their order in the reporting form, and how they were to be analysed. To estimate whether the reporting rate had risen or fallen during the pilot period compared to previous and

particular time points, the proportions were subjected to exact test for two dichotomous, independent variables. This was preferred to the Chi squared test which cannot be used when the expected values (in a contingency table) have insufficient data, or in this scenario, zero values (Bowers, 2002). This approach to analysis was reviewed and agreed by a medical statistician.

Table 8.3: Analysis of variables in mini-pilot reporting scheme

Variable	**Method of analysis**
1.Location of error	Descriptive quantitative: total by location and as each location as percentage of all pilot locations. Assess increase/decrease in reporting rate by comparison of number of reports submitted by reporters during the pilot period compared to: • 3 months period prior to pilot • 1 year prior to pilot • 1 year and 3 months prior to pilot (Using Fisher's exact test)
2. Date of error	Descriptive quantitative: to demonstrate any trend by day
3. Time of error	Descriptive quantitative: to demonstrate any trend by time
4a. Patient informed (Yes/No)	Descriptive quantitative: total/percentage of patients informed/not informed
4b. Relative informed (Yes/No)	Descriptive quantitative: total/percentage of relatives informed/not informed
Variable	Method of analysis
5. Patient Harm (Yes/No)	Descriptive quantitative: total/percentage of patients sustaining harm
6a. Profession of person closest to error	Descriptive quantitative: total/percentage of persons closest to the error by profession
6b. Profession of report (if different)	Descriptive quantitative: total/percentage of reporter by profession
7. Stage at which error occurred	Descriptive quantitative: total/percentage of errors by stage of delivery to patient
8. Outcome	Descriptive quantitative: total/percentage of near misses compared to adverse events
9. Circumstances (free text)	Descriptive qualitative: • any value had been added in relation to the context of the error and its causation • there was an emphasis on individuals or systems, or both • there was any evidence of blame • any differential characteristics existed according to profession or clinical location

Variable	Method of analysis
10. Drug name	Descriptive quantitative: total numbers of drugs by identified name
11. Drug error type (select option)	Descriptive quantitative: total numbers of errors by type and ranking order
12a. Contributory factor (select option)	Descriptive quantitative: total numbers of contributory factors by frequency of occurrence[1]
12b. Contributory factor: importance	Descriptive quantitative: median score and inter-quartile range
12c. Contributory factor: (free text)	Descriptive qualitative: any value had been added in relation to causation
13. Action taken (select option)	Descriptive quantitative: options for action taken by frequency of occurrence and ranking order
14. Preventative measures taken (free text)	Descriptive qualitative: • any value had been added in relation to the context of the error and its causation • there was an emphasis on individuals or systems, or both • there was any evidence of inherited blame • any differential characteristics existed according to profession or clinical location

1. If possible, any relationship between specific error types and contributory factors would also be explored, other studies having previously demonstrated that particular error types stem from specific factors (Alnutt 1987, Buckley et al 1997).

8.7 Conclusion

This chapter has described the methods employed to design the enhanced reporting scheme and how it was piloted. The design was based on general and specific considerations. The latter have been addressed through tabulating the rationales from the literature and empirical data, for each component of the report form proper and the supporting guidance. Particular attention has been given to the structure for reporting the contributory factors, and how this was decided. The recruitment of clinical units has been explained. The training process, instrumental to the implementation of the mini-pilot, was described in detail. The findings from Stage three of this study are presented in the following chapter.

CHAPTER 9: FINDINGS FROM THE PILOTING OF AN ENHANCED REPORTING SCHEME FOR DRUG ERRORS

9.1 Introduction

This chapter presents a summary of the key findings from the mini-piloting of the enhanced reporting scheme over a three month period in six clinical departments. The quantitative findings are presented first, followed by the qualitative findings. The quantitative analysis focussed on the numerical data from each section of the report form judged as relevant to the research questions. These were:

- Reporting rate within the three month pilot period
- Comparative reporting rates by pilot unit [speciality] over the duration of the pilot
- Reporting rate by profession
- Reporting rate by time of day
- Reporting rate by stage of drug delivery [e.g. prescribing, dispensing, administration]
- Number of definitive drug errors
- Frequency of drug error types
- Frequency of drug error outcomes
- Frequency of contributory factors and their importance (1-10) as attributed by the reporter
- Type and frequency of action taken

The qualitative analysis was based on the free text used to describe the circumstances of the error (Report Form Box 9), and the free text used to describe action taken (Report Form Box 14). To assess value added by the enhanced scheme, the primary and sub categories created in the Stage 1 data analysis were used to identify and appraise any brief or detailed reports.

9.2 Quantitative findings

The duration of the mini-pilot was three months (93 days), from 27.6.06 until the 27.9.06. During this time 49 reports were submitted from the following clinical departments:

- Care of the Elderly: two wards
- Neonatal Unit
- Oncology Ward
- Surgery: two wards
- Pharmacy Dispensary

The reporting rate over the three months (in two week periods) is shown in figure 9.1 below, the bulk of reporting having occurred in the first month.

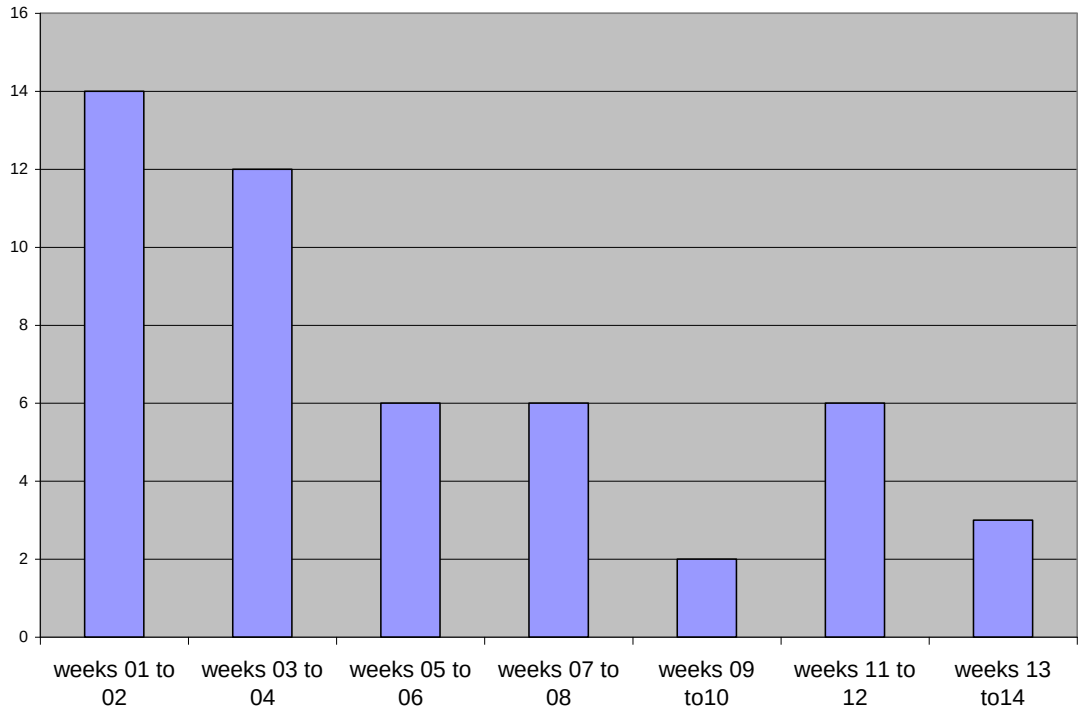


Figure 9.1: All submitted definitive drug errors reports by 2 week periods during pilot study

The number of reports submitted from each of the clinical departments is shown in Table 9.1. This period is compared to the three month period immediately prior to the pilot, the three month period 1 year prior to the pilot, and finally in the three

months preceding this period. First it can be seen that the total number of reports submitted from all the clinical locations included was greater than two out of the three previous periods. There was little change in the proportion of reports submitted by the Elderly Care wards compared to previous periods (excluding the period 27.6.05 – 27.9.05), and Fisher's exact test confirmed that this was not statistically significant (p = 0.616). Although the number of reports submitted by the Neonatal Unit during the mini-pilot period is noticeable for accruing more than a third of the total number of reports, there was a significant fall in the proportion of reports submitted compared to the previous periods (p = 0.025). The proportion of reports submitted by the Oncology ward also fell, but this was not significant (p = 0.511), however the Surgical wards saw a statistically significant rise in the proportion of reports submitted (p = 0.001).

Table 9.1: All reports submitted by the pilot specialisms/units during the pilot and in three other 3 month periods prior to the pilot (including the dispensary where 3 reports originated concerning drugs supplied to one of the clinical locations in the pilot)

Clinical location	**Number of reports submitted in the pilot period using the enhanced scheme 27.6.06 - 27.9.06**	**Number of reports submitted using the established scheme 1.3.06 - 1.6.06**	**Number of reports submitted using the established scheme 1 year prior to the pilot 27.6.05 - 27.9.05**	**Number of reports submitted using the established scheme 1.3.05 - 1.6.05**
Elderly Care	7 (14.3%)	7	0	8
Neonatal Unit	19 (38.8%)	22	17	35
Oncology Ward 15	6 (12.2%)	10	3	8
Surgery	14 (28.6%)	4	6	2
Dispensary	3 (6.1%)	Figure not available	Figure not available	Figure not available
Totals	**49 (100%)**	**43**	**26**	**53**

Table 9.2 below demonstrates the reporters by profession but also by clinical base. The neonatal unit has submitted the most reports as previously shown but it also has the most doctors submitting. Nurses remain the predominant group of reporters. Pharmacists submitted the same number of reports as doctors which is a relative percentage increase on the number they submitted in the period studied in

Stage 1 as they had then largely used another (pharmacy-based) reporting scheme.

Table 9.2: Reporters of definitive drug errors by profession and clinical location during the 3 month mini-pilot period [*excluding 3 from dispensary]

Clinical unit/ward	Doctors	Nurses	Pharmacists	Total
Care of the Elderly Ward 3	0	3	0	3
Care of the Elderly Ward 6	0	4	0	4
Neonatal Unit	4	15	0	19
Oncology Ward 15	3	2	1	6
Surgical Ward 8	0	6	3	9
Surgical Ward 11	0	2	3	5
Totals	7 (15.2%)	32 (69.6%)	7 (15.2%)	46 (100%)*

Tables 9.3, 9.4, and 9.5 show the reporters by profession in the same three time periods previously compared.

The most common protagonists (person closest to the error, n=53) by profession were doctors (24/45.3%), followed by nurses (18/34%) and pharmacists (11/20.7%). In some errors however, there was more than one protagonist and these could be from different professions, for example nurses and doctors were jointly involved in the error chain on seven occasions. Pharmacists were never jointly involved with doctors. Of the doctors who were protagonists, one was at consultant level.

Table 9.3: Reporters of definitive drug errors by profession and clinical location in the 3 month period prior to the mini-pilot: 1.3.06 - 1.6.06

Clinical unit/ward	Doctors	Nurses	Pharms	Unknown/other	Total
Care of the Elderly Ward 3	0	1	1	0	2
Care of the Elderly Ward 6	0	4	0	1	5
Neonatal Unit	0	22	0	0	22
Oncology Ward 15	0	7	1	2	10
Surgical Ward 8	0	4	0	0	4
Surgical Ward 11	0	0	0	0	0
Totals	0	38	2	3	43

Table 9.4: Reporters of definitive drug errors by profession and clinical location in the 3 month period 1 year prior to the mini-pilot: 27.6.05 – 27.9.05

Clinical unit/ward	Doctors	Nurses	Pharms	Unknown/other	Total
Care of the Elderly Ward 3	0	0	0	0	0
Care of the Elderly Ward 6	0	0	0	0	0
Neonatal Unit	3	14	0	0	17
Oncology Ward 15	1	2	0	0	3
Surgical Ward 8	0	5	0	0	5
Surgical Ward 11	0	1	0	0	1
Totals	4	22	0	0	26

Table 9.5: reporters of definitive drug errors by profession and clinical location in the 3 month period prior to the period 1 year prior to the mini-pilot: 1.3.05 - 1.6.05

Clinical unit/ward	Doctors	Nurses	Pharms	Unknown/other	Total
Care of the Elderly Ward 3	0	4	0	1	5
Care of the Elderly Ward 6	0	3	0	0	3
Neonatal Unit	3	31	0	1	35
Oncology Ward 15	2	5	1	0	8
Surgical Ward 8	0	0	0	0	0
Surgical Ward 11	0	1	1	0	2
Totals	5	44	2	2	53

The chart below shows the time of reported errors collated into 2 hour periods from 10am. No errors were reported between midnight and 6 am. The majority of reports were submitted in the period between 08.00 and 14.00 hours, but not all reports had recorded the time of an error.

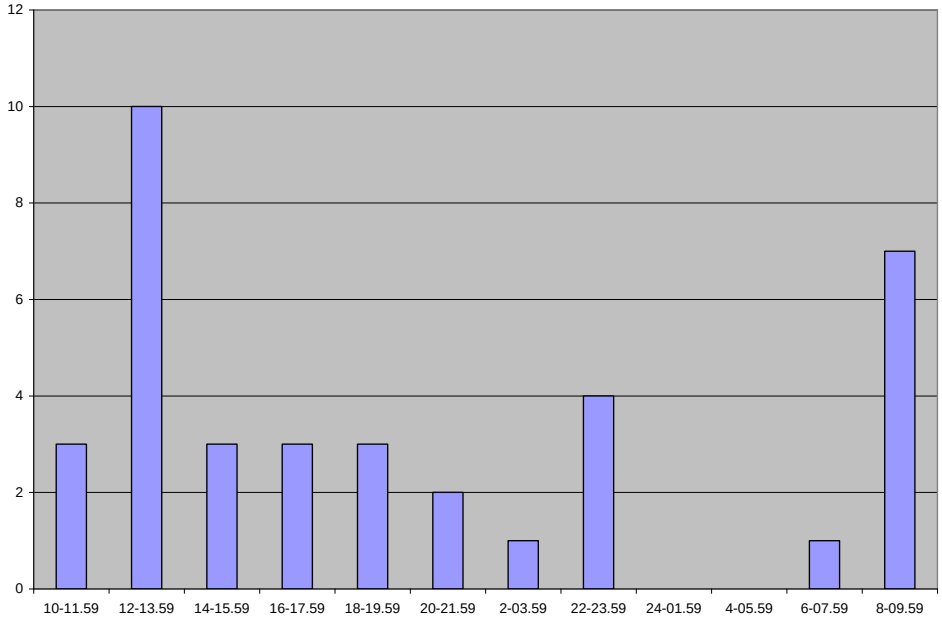


Figure 9.2: Dispersion of definitive drug errors over 24 hour period (by 2 hour intervals)

Unlike the traditional reporting form, the enhanced form specifically asked for the stage at which the drug error occurred but not all reporters provided this data. However, it can be deduced that some errors were made at more than one stage; see table 9.6 below, which also suggests evidence of vicarious reporting.

Table 9.6: Errors by stage of drug delivery and profession of reporter

Stage of drug delivery	Definitive error occurrence	Profession of reporter		
		Doctor	Nurse	Pharmacist
Prescribing only	11	2	5	4
Dispensing only	7	0	4	3
Administering only	12	0	12	0
Prescribing & administering	12	3	9	0
Prescribing and dispensing	0	0	0	0
Dispensing and administering	1	0	1	0
Prescribing, dispensing and administering	2	1	1	0
Grand Total	45[1]	6	32	7

[1]NB one error was reported by a junior doctor but was a manufacturer error which accounts for total error count being 45 rather than 46.

In the mini-pilot, all submitted reports should have been based on definitive drug errors, as this was a drug error reporting scheme only, and the NCCMERP definition available to all reporters through the printed guidance accompanying the report. On four occasions, the reporters did not identify whether a reported incident

was an error, and the author found insufficient data to attribute a 'yes' or 'no', again on four occasions, but these were different cases. Table 9.7 provides a breakdown of drug errors/non-errors, as attributed by the reporter and then the author.

Table 9.7: Reporters' / Authors' counts of drug errors/non drug errors in all reports

Error / Non-error	Reporter	Author (GA)
Definitive drug error	42	42
Not a drug error	3	3 (1 case mutually agreed)
Blank	4	0
Insufficient data to define	0	4 (different cases to blanks)
Totals	49	49

Having decided whether the case was a drug error or not, the reporters were then asked to decide if the outcome was a near miss or adverse event by ticking accompanying 'yes' or 'no' boxes in the subsequent section. Again, reporters had access to formal definitions of near misses and adverse events. It can be seen from table 9.8 that reporters judged 22 reports to be near misses, and 12 not. On 15 occasions the reporters did not offer a 'yes' or 'no' response (blank) on either of the error outcomes, in spite of classifying the case as a drug error. The single adverse event was also entered as a near miss.

Table 9.8: Reporter classification of drug error outcome

Error outcome	Yes	No	blank	Totals
Near miss	22	12	15	49
Adverse event	1	33	15	49

The author's classification of drug error outcomes from an analysis of the free text, without sight of the reporter's original classifications, and using the same definitions, differed considerably (see table 9.9). Reporters classified 22 (44.9%) of the outcomes as near misses whereas the author classified 42 (85.7%) outcomes as near misses. The four blank entries were those cases judged to have insufficient data to define the outcome. In three reports it was decided that the incidents were not definitive drug errors.

Table 9.9: Author classification of drug error outcome

Error type	Yes	No	blank	Totals
Near miss	42	3*	4	49
Adverse event	0	45	4	49

* not definitive drug errors

In view of the lack of agreement, an independent review of drug error outcomes was performed by one of the study supervisors. The reviewer was given all the free text entries from the 49 completed reports, and the definitions of drug error, near miss, and adverse event made available to reporters. He was blinded to the author's original judgements. The results (table 9.10) showed 100% agreement with the researcher's classification.

Table 9.10: Independent reviewer's classification of drug error outcome

Error type	Yes	No	blank	Totals
Near miss	42	3*	4	49
Adverse event	0	45	4	49

* not definitive drug errors

9.2.1 Error types

A total of 46 error types have been included in table 10.11 as this was the original number of drug errors with error types, described by reporters. Whilst wrong drug and drug omission errors appear the most numerous, collating all the dosing errors under one heading would make this the most prevalent (n=16 cases). The highest number of reported dosing errors was received from the neonatal unit (8 or 50% of the total). The most common drug group type in the reported errors was analgesics (9) followed by antibiotics (4). A wide range of drugs was apparent.

Table 9.11: Definitive error types and frequency

Error type	Frequency
wrong drug	10
drug omission	8
overdose	8
extra dose	4
underdose	4
labelling error	2
monitoring error	2
other	2
wrong time	2
drug expired	1
unknown	1
wrong patient	1
wrong rate	1
Grand Total	46

9.2.2 Contributory factors

Just one report did not identify any contributory factors, this having been completed by someone who was absent from the immediate environment where the error had occurred. Contributory factors are shown in figure 9.3 below by the number of times they were individually identified (frequency of occurrence).

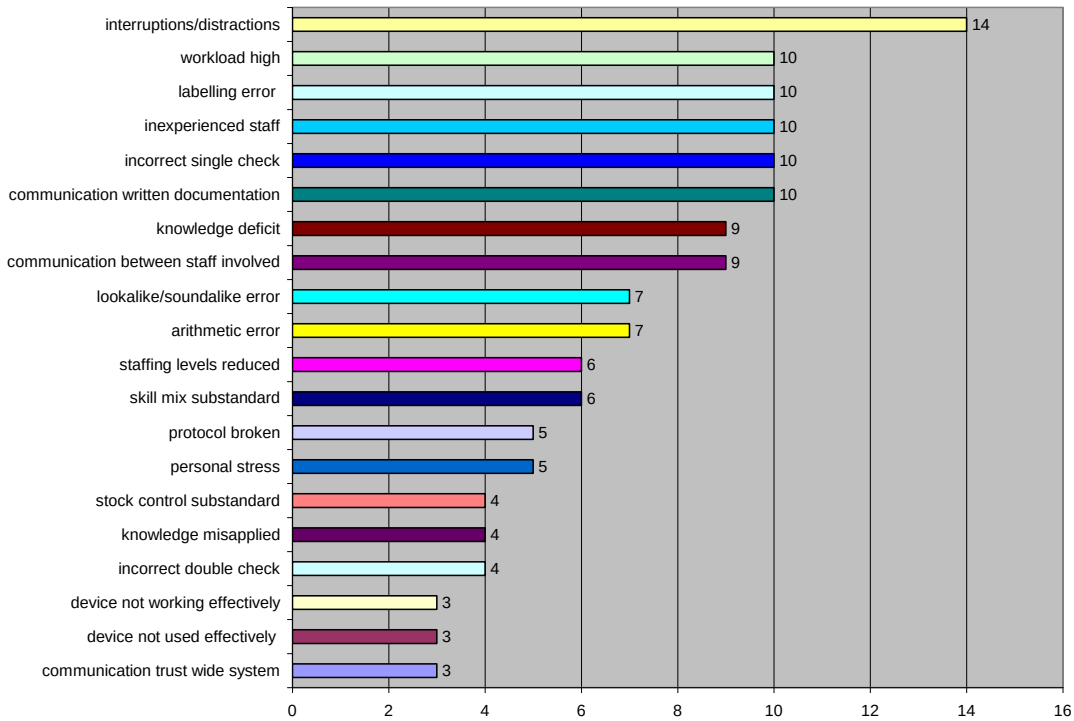


Figure 9.3: Frequency of contributory factors in definitive errors (%)

Table 9.12 shows the scores attributed by reporters to each of their identified factors. The median score is shown for each factor and where the contributory factor occurred 5 or more times, the inter-quartile range. A bimodal distribution is apparent. However, three reporters ticked all of the boxes and attributed a score of 1 to the majority of factors, which skews the dispersion. As they also ticked the two factors concerning devices when there was no evidence of devices having been used (and no device number recorded), this suggested an error in completing the report form.

Table 9.12: median and inter-quartile range for the strength of each contributory factor as attributed by the reporter.

Contributory factor	Frequency of occurrence	Strength of factor				
		MIN	Q1	Median	Q3	MAX
Arithmetic error	7	1	1	**10**	10	10
Communication trust wide system	3	1		**2**		10
Communication between unit/ward staff involved	9	1	1	**8**	10	10
Communication written documentation on unit/ward	10	1	1	**7**	10	10
Device not used effectively	3			**1**		
Device not working effectively	3			**1**		
Incorrect double check	4	9	9	**10**	10	10
Incorrect single check	10	1	1	**10**	10	10
Inexperienced staff	10	1	1	**7**	10	10
Interruption/ distraction	14	1	6	**8**	10	10
Knowledge deficit	9	1	1	**10**	10	10
Knowledge misapplied	4	1		**1**		5
Labelling error	10	1	1	**10**	10	10
Lookalike/ Soundalike error	7	1	1	**1**	9	10
Personal stress	5	1	1	**1**	8	8
Protocol/policy broken	5	1	1	**1**	9	10
Skill mix substandard	6	1	1	**8**	9	10
Staffing levels reduced	6	1	1	**3.5**	7.5	8
Stock control substandard	4	1		**4.5**		10
Workload high	10	1	4	**7**	9.5	10

The patient was informed of the error on eight occasions. However, this figure should be interpreted with caution as patients on the neonatal unit could not be informed for obvious reasons. Moreover, since all of the errors were actually near misses, it is arguable whether the patient would need to know.

9.2.3 Action taken

One month after the close of the mini-pilot, 11 reports remained with the respective unit managers for reporting 'action taken', thus the findings below are drawn from a sample of 38 errors. In the tick box options for 'action taken: immediate' there were 31 responses (see table 9.13), however managers did not necessarily have to choose from any of the listed options. In action taken related to feedback (discussion and dissemination of the error for learning), managers could have potentially chosen up to 4 options for each error. Table 9.14 shows that of the 22 cases where the reporters were seen by their manager for feedback, 11 were accompanied by interpersonal support for those involved. The content of the free text box allied to the action taken section was indicative of the preventative nature of action taken, and is discussed further below.

Table 9.13: Action taken: Immediate

Action taken	**Frequency**
Interpersonal support for those involved	11
Supervision	5
Education / training	10
Systems review	4
Medical device change	1
Totals	31

Table 9.14: Action taken: Feedback for learning

Action taken: Feedback	Frequency
Discuss with the person closest to the error	22
Discuss with the ward unit team	19
Discuss at the local risk or clinical governance forum	8
Disseminate any learning to all trust staff	4
Totals	53

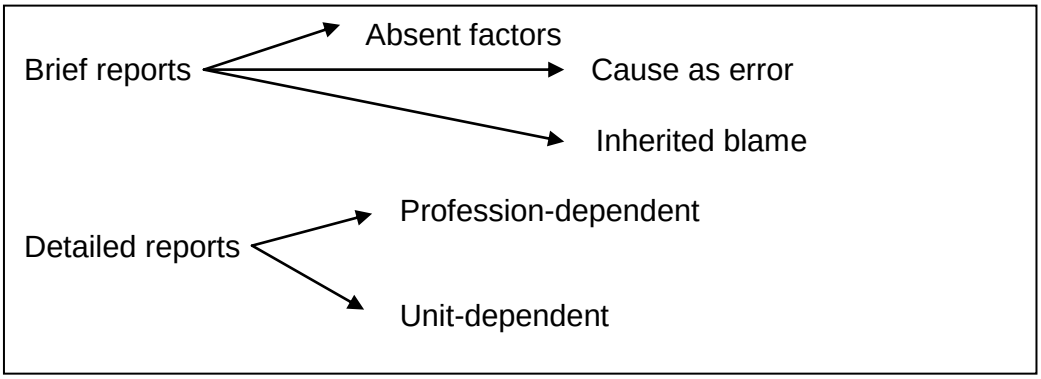
9.3 Qualitative findings

Mindful of the analysis of the previous report data from stage 1, the key aim here was to examine the content and nature of the data to assess whether:

- any value had been added in relation to the context of the error and its causation;
- there was an emphasis on individuals or systems, or both;
- there was any evidence of blame,
- any differential characteristics existed according to profession or clinical location.

The primary and sub categories that emerged from the Stage 1 data are shown in Figure 9.4 below and were used to compare and contrast the findings between Stages 1 and 3 of the study.

Figure 9.4: Stage 1 primary and subcategories in data analysis



9.3.1 Brief reports

9.3.1.1 Absent (contributory) factors

Of course, a strict comparison with the Stage 1 categories was difficult as a definitive list of contributory factors was provided to reporters within the pilot format. Consequently, and as detailed, factors were identified in all but one report using this list. However, 12 (26%) of the 46 definitive error reports were judged to have so little free text that assessing the context of the error (the elements of the report asked for in 'circumstances') solely from the report would have been impossible. Of these 12 reports, two were from the neonatal unit, five from the two care of the elderly wards, and five from the two surgical wards. This may point to the neonatal unit staff's inclination not only to historically report at a greater rate than other units/wards, but also to provide more data. However, two of the surgical ward reports were of the kind where context would be difficult to establish as the reporters were not the protagonists and outside of the department where the error was made, for example:

[Reporter]: 'Glicazide 20mgs tablets dispensed instead of glicazide MR – labelled correctly. Patient hasn't taken any of the medication. (17/06 – reported by ward pharmacist, Ward 8)

Furthermore, the increased detail apparent in the majority of reports also sometimes included, encouragingly, an acknowledgement from the reporter that the data on causation might be insufficient:

[Reporter]: *'Ward 11 contacted pharmacy. Medication box transferred with patient from ward 20 with felodepine SR 5mgs which contained finasteride 5mgs. Concerned that patient may have received wrong drug. Ward staff confident that they gave correct drug. Action: checked pharmacy computer, only finasteride dispensed on 3.7.06 for another patient. Wrong medication also dispensed to patient, cannot determine source of error'* (201/06)

9.3.1.2 Misplaced factors and cause as error (misinterpreted factors)

The design of the enhanced, pilot form appeared to prevent these previously problematic features of report writing recurring. Factors were discussed in 'preventative measures to be taken' but only as a reiteration of the factors previously identified from the available list. None of the errors reported summarily identified the cause as error [e.g. cause – human error]. The term 'human error' was used once but in 'preventative measures' to consolidate what had been carefully described as a 'wrong time' checking error, involving written miscommunication, and inexperienced staff:

Preventative measures: (Ticked boxes) *Interpersonal support for those involved, discuss with ward team, discuss with person closest to error.* (Text) *Discussed with staff administering drugs importance of reading the drug chart correctly, the dose was correct and frequency incorrect, it should have been 4 hourly. The nurse involved gave it 4 hourly because this was the norm. This was human error'* (470/06)

9.3.1.3 Inherited blame (and profession-dependent detail)

Blame was not apparent in any of the free text in submitted reports neither explicitly nor implicitly, nor were the terms (or words associated with) 'disciplinary action' or 'counselling'. However, individual protagonists were named in the circumstances for eight reports (all nurse reporters). This did not seem to contribute to any causal analysis apart from report 457/06 where perhaps for accountability reasons, a near miss was reported which involved a nurse who was awaiting new spectacles, and due to temporary sight problems, was to have all drugs checked with another prior to administration. The difference in style according to the profession involved was less obvious. There was also a collective emphasis on a more systems-orientated approach, and error prevention:

Circumstances [a protagonist]:*'Staff nurse T asked me to check a drug with her.*

Drug she wished to check was sodium chloride, however she brought sodium phosphate which I informed her was wrong. She then brought sodium valproate to be checked at which point I told her that sodium chloride was kept in the fridge. Preventative measures [text]: *discussed with protagonist the importance of reading the labels of prescribed drugs and ensuring it is the correct bottle. She has recently undergone drug calculation training (workbook) on essential training day. She is aware that she needs to have drugs checked and always does so. I offered her further supervision, she is awaiting new spectacles.* Action taken [boxes ticked]: *Interpersonal support for those involved, education/training, supervision, discuss with person closest'* (457/06, Senior Nurse)

Circumstances [protagonist]:*' 'Syringe driver containing metaclopramide 30mgs, ordered from pharmacy for patient X, the syringe was dispensed form pharmacy but labelled with another patient's name. This patient not on this medication. Syringe disposed of.* Preventative measures [text]: *discussed with unit pharmacist – incident indicates that he is doing too much and that's when errors occur. He hopes that this will highlight the problem with his managers that he is doing too much. Incident copied to pharmacy.* Action taken [boxes ticked]: *Interpersonal support for those involved, systems review, discuss with person closest to the error'* (308/06, Pharmacist)

Circumstances [protagonist]: '*patient on long term warfarin usually INR monitored in warfarin clinic. Recently started on his first cycle of capecitabine oral chemotherapy. As this can interact with warfarin, INR taken on ward 15 at 10 days (10th July) – results form states that correct result (5.6) was made known to ward (ward informed). Result arrived on my desk the following day. Believing appropriate action had been taken, I signed the form and left it for filing. But no action had been taken.*

Preventative measures [text]: *staff reminded of importance of passing on and*

acting upon results. Patients to be reminded to telephone results or wait in unit until received. System to be introduced whereby any member of staff taking results by phone signs and specifies who they are and what action they have taken.
Action taken [boxes ticked]: *Education/training, discuss with ward team, systems review'* (302/06 Senior Doctor)

Finally, as reporters had been encouraged in the written guidance to identify, in a near miss, 'why something didn't happen', all near miss reports were analysed for text concerning error recovery, so as to prevent an adverse event. Such recovery data was though only evident in just 5 of the reports, the most vivid being:

[Reporter]'mum reported to sister A that her daughter was nearly given a second dose of oramorph. Staff nurse X had come a minute earlier and given the baby her dose of oramorph. Staff nurse Y come a minute later with a syringe in her hand. Mum asked what she was going to give. When told morphine, she said she had just had it. Staff nurse Y apologised, and said she wasn't going to give it. Mum reported her concerns to sister A, who spoke to her' (46306)

9.3.2 Detailed Reports: Profession and Unit-dependent detail

In the free text concerning circumstances (and the supplementary text box for contributory factors), factors and contextual information were cited in 22 out of the 46 (47.8%) definitive drug error reports. Two examples below from the contrasting clinical areas of neonatal care and care of the elderly demonstrated relevant but concise detail. In the first report, the vicarious reporter recognised the multi-professional nature of the error:

Circumstances [reporter but not protagonist]: *Prescribing, dispensing and administration error by staff nurse. Heparin was prescribed on main chart, not anticoagulant chart. Prescription did not follow trust guidelines on using undiluted heparin 1000units/ml. Syringe subsequently diluted using the 1000 units /ml strength leading to underdose of heparin. Action taken (text): one to one*

discussion with staff involved – practice with drug calculations. Look at skill mix on night duty.

Action taken (tick boxes): IPS support, education/training, discuss with ward team, supervision, discuss with person closest' (25606) Senior Nurse

'Dalavit was either not given or not signed for on the 17th July. It appears that the nursery nurse went off sick during the shift and care was taken over by another staff member. Workload high on the night shift and was taken over by a midwife helping from delivery suite.

Action taken: discuss with unit. Staff reminded via newsletter that communication/documentation essential. Part of handover/safety checks to check medication chart and drugs that are due/should have been given'
(46206) Senior Nurse

9.4 Conclusion

The data provided in the enhanced reports provided categorical information on: error rates, where the error(s) occurred in the process of drug delivery, the drug implicated, error type, outcomes, contributory factors and the strength of their influence. Importantly, there may have been problems with reporter's understanding of the terms 'near miss' and 'adverse event'. Furthermore, while there also appeared to be a more comprehensive coverage of the circumstances around the error, and despite written guidance being available as part of the reporting process, some free text remained so brief as to render any contextual detail impossible. There was also a lack of data on faulty cognitive processes. However, the absence of blame and blame language was notable together with a stronger systems orientation, although the propensity to mention practitioners' names remains and may be indicative of a residual inclination to take a person-centred, rather than systems approach. It should not, however, be concluded that this apparent shift in attitude and understanding about causation is related to the

enhanced scheme alone, it is suggested that the role of training was also influential, the author having learned that many staff knew relatively little about the concept of error, drug errors and multi-factorial causation.

9.4.1 Mini-pilot report format: recommended practical changes

Practical difficulties related to the design of the enhanced report form may have also influenced the performance of reporters. A number of points emerged from the immediate analysis, and there was also a number of comments received from clinical governance leads and unit managers on practical considerations.

1. the term ‘drug error’ as a yes/no tick box in Box 7 appeared to be confusing and may have contributed to confusion with the near miss tick box immediately below
2. the request for reporters to detail whether the error was ‘prescribing, dispensing, administration’ in Box 8 was often missed
3. there was no error type covering ‘drug unavailable’ when a drug was needed by either pharmacy or a ward/unit for general stock rather than a specific patient, so it seemed to be assumed that the consequence of this [e.g. ‘drug omission, or ‘wrong time’] was the error type, which was inappropriate
4. a ‘stop’ marker would need to be placed in emboldened text at the end of the section for reporters
5. an additional ‘action taken’ option may have to be ‘root cause analysis’
6. a date is required for the person taking action to show when the action was suggested
7. a contributory factor specifically related to the ‘patient’ should be included

CHAPTER 10: DISCUSSION

10.1 Introduction

This study has gathered data from a range of sources to generate a better understanding of drug errors, and their reporting to ultimately develop an enhanced reporting scheme. A detailed analysis of the background literature on human error and incident reporting has illuminated the research topic, its context and theoretical underpinning. An additional systematic review has identified gaps in the empirical knowledge base that require further study and also supplied a rationale for the chosen methodology. The empirical data, gathered from two contrasting but complementary sources has provided a valuable, multi-disciplinary perspective on the factors that give rise to drug errors and the process by which they are, or conversely are not, reported. Moreover, these data have been synthesised to construct an evidence-based drug error reporting scheme which has been subjected to a formal evaluation through a mini-pilot.

This chapter first presents an integrated discussion of the key findings from stages one and two of the study, their relationship with the existing literature and implications for understanding drug errors and their reporting. The content is organised under the following thematic headings:

- Drug error reporting
- Contributory factors in drug errors
- Reporting culture
- Inter-professional considerations
- Organisational and societal considerations

Secondly, the findings from the mini-pilot (stage three) are discussed. Thirdly, the

validity and reliability of the findings, together with the implications for method and theory, are then considered through addressing the study's strengths and weaknesses. Finally, an overall conclusion accompanies several recommendations.

10.2 Discussion of the key findings from Stages One and Two

10.2 .1 Drug error reporting

The epidemiology of drug error reporting is an imprecise science and the stage one data reinforces this on several counts. The necessary exclusion of 262 drug incident reports from the stage one analysis, that were inappropriately coded by the trust as drug errors, suggest their data were originally ordered and without operational definitions. A similar phenomenon was experienced by Miller et al (2006) in their retrospective report review where 21% of what were ostensibly coded as drug error reports in their sample were, following detailed analysis, excluded. Secondly, and as in all studies of error reporting, the findings from the retrospective report analysis do not provide an error rate but simply a drug error reporting rate. However, the increasing rate of reporting over the five year period studied may be suggestive of a greater awareness of the value of reporting among healthcare professionals, and is reflective of the British national trend as cited by the National Audit Office (NAO, 2005). The proportion of errors reported that were near misses (26%) is somewhat higher than the 20% estimated by the NAO (2005) for acute trusts in the UK which is also encouraging, especially knowing that near miss reporting is typically uncommon despite its value in uncovering the nature of error rescue (Kaplan & Fastman, 2003, Evans et al 2006). A reporting system should not, however, be evaluated on the basis of reports received but on the quality of information, and its ability in 'identifying vulnerabilities' (Bagian et al 2001, p524).

Unlike definitions of drug error, anomalies have rarely been seen in defining drug error type (Ross et al 2000). The most common reported error type identified here was dosing error (26.94%) and is reflective of the findings in other studies using a range of methods (Bates et al 1995a, Bates et al 1995b, Lesar et al 1990, 1997) – including incident report analyses (Selbst et al 1999, Ross et al 2000) - although these were in paediatric settings.

10.2.2 Contributory factors

While the associated inter-rater agreement on error type was very good, agreement on contributory factors was less impressive. The conceptual confusion that can arise around causation is a substantial challenge to both reporters and risk managers. For example, is a written miscommunication such as an illegible prescription the cause of an error or the effect of a systems problem such as reduced staffing and high workload? The inter-rater process clarified the potential problem in using even specifically tailored terminology. The host trust's apparent confusion over their coding of a drug error is perhaps less surprising mindful of some of the issues with inter-rater agreement unearthed here.

The author, as primary rater was also less inclined to attribute the value laden NCCMERP term 'performance deficit' as a contributory factor than the secondary raters – in fact more inclined to classify most of the same cases as having 'unknown' factors. How objectively the same sort of factor might be attributed by other members of the organisation, knowing that causation in the existing reporting scheme was attributed by managers, and that there was clearly confusion over what was an error, is likely to be a concern. While achieving high reliability in agreeing definitions of an adverse event might be elusive (Walshe 2000), it would seem the attribution of cause may be also challenging. The process of measuring inter-rater agreement also highlighted a weakness in the NCCMERP taxonomy. Error causation is often predicated on external manifestations which inadvertently neglect the cognitive processes of those present (Kostopoulou, 2006). This

indicates that taxonomies require a systematic, theoretical foundation to allow an understanding of the mechanisms inherent in error (Zhang et al 2004; Kostopoulou, 2006). The NCCMERP taxonomy lacks such a foundation, the consequences of which may lead to the inadvertent assignation of blame.

That 27.8% of reports in the stage one data did not bear any data on contributory factors was a clinically significant finding. It was also seen that particular error types such as 'drug to drug allergic patient' seemed especially prone to lacking contributory factors, which might appear surprising considering the catastrophic medication error (see pages 115,126) resulted from giving a known drug allergic patient the allergy-causing drug. The leading *identifiable* contributory factors were concerned with inter-professional communication (both written and verbal) – known to be one of the most common contributory factors from a diverse range of studies but especially in those concerning prescribing and administration. Reports received by the NRLS have also shown communication problems to be common across many different types of incidents (NPSA, 2005a). Sutcliffe et al (2004), using qualitative interview data, but from 26 randomly selected junior doctors, confirmed communication difficulties to be one of the leading factors in medical error. Of interest is that Sutcliffe et al proposed that openness and quality of communication – co-incidentally two maxims of patient safety – are often overshadowed by concerns about hierarchy and power. Again employing qualitative interviews, Dean et al (2002b) found that poor communication of treatments was viewed by junior doctors as a key factor in the genesis of prescribing errors. Other studies (Taxis & Barber 2003, Sanghera et al 2007) illuminate very particular inter-professional communication failures between health professionals in medicines management such as receiving ambiguous prescriptions. Accordingly, it would seem that inter-nurse communication also warrants attention. Albeit in a simulated study, Kazoaka (2007), like Sutcliffe, has shown that communications are impaired by an unconditional respect for rank

authority, and that those who continuously work together are less likely to confirm facts before drug administration. The stage one analysis strongly suggested that while poor inter-professional communication was a frequently reported factor, there was little information about the factors with which it might co-exist. Such findings provided a strong rationale for the subsequent interviews as a means of establishing more contextual knowledge on causation, but again point to serious misgivings in report data. It follows that establishing knowledge of any relationship between contributory factors and error types was equally difficult for the same reasons. This may have been partly attributable to reporting via a generic scheme (rather than one specifically tailored to drug errors). It was also worth postulating whether a lack of structured prompts for reporters, the presence of which has yielded more data elsewhere, such as in the AIMS study (Malpass et al, 1999a & 1999b), was a handicap.

The interview participants also identified a series of contributory factors which broadly accorded with the NCCMERP (1998) terminology, but additionally demonstrated their inter-relationship, emphasising that they existed at different levels, from the direct interface with patients to the broader organisation as theorised by Reason (1990, 1997, 2000).

The contributory factors are now discussed as described by the participants, although in view of the many factors cited, only the most commonly cited factors are addressed in detail. These factors were also evident in the systematic review (See Table 3.2), they are:

- high workload
- poor communication deficits
- interruptions
- knowledge deficit
- faulty cognitive processes
- inappropriate attitudes
- double checking

Woods & Cook's description of the healthcare environment being replete with multiple pressures, uncertainty, and finite resources chimed with many of the participants' descriptions (Woods & Cook 2003). High workload was, by some margin, the most frequently, and most emotively discussed, factor. An uncontrolled workload adds support to Reason's explicit acknowledgement of workload as a significant error-producing condition, having been germinated by latent failures (Reason 2000). It deflects attention away from the individual and towards systems, sharpening the focus on the organisational commitment that Carthey et al (2001) have argued is necessary for *collective* error wisdom. It has also been claimed that if workloads are reasonable, staff are less likely to migrate from safe behaviours or protocols (Fogarty & McKeon 2006). Nevertheless, it is by definition, a controversial factor, highlighting the perennial priority battle between production and safety (Reason 1990, p203), that is following NHS reforms, probably as pertinent now to the NHS as private industry (West, 2000).

High workload has been previously identified using quantitative and qualitative approaches, and from a multi-centred incident report analysis (Roberts et al 2002). Furthermore, the systematic review also showed that workload was a multi-disciplinary issue (Dean et al 2002b, Gladstone 1995, Peterson et al 1999, Tang et al 2007, Tissot et al 2003); however, a detailed inspection of some of the studies does demonstrate some issues of validity. For example, having distributed a questionnaire using snowball sampling, Tang et al (2007) may have inadvertently created a sampling frame of like-minded individuals each endorsing each others beliefs that high workload is a perennial, root cause of drug error. In these data, workload was often described in the context of chaos, which seemed most likely to affect nurses, and critically this view was shared by their multi-disciplinary colleagues. Nevertheless, a potential threat to validity in any future reporting scheme would be some reporters developing a natural inclination to default to high workload as a singular cause of drug error – whatever the role of unsafe acts –

thereby promulgating the favourable image that has been previously discussed (p62) as a threat to the validity of such interview data.

Conversely, ways of working were also seen here as influencing nurses' workloads - again by nurses, but also their multi-disciplinary colleagues. While the participants clearly did not subscribe to the position that errors stem from erratic people who undermine the systems they work in (Woods & Cook 1999), their view does add weight to the Government's demand for reform as well as investment as part of the NHS Plan (DoH 2000b). Finally, some participants also recognised that a low workload could, through lack of stimulation, also be an error-producing condition; a view that bears out the threat of familiarity and habituation to human attention (Sternberg 2003).

As has already been discussed, problematic communication was a leading factor in the documentary analysis of drug error reports and the interview data would seem to confirm this, adding useful contextual information. Leape et al (1995) have argued that, like many other factors, problematic communication is basically about impaired access to information (p41). Considering the multi-ethnic nature of the local population and the associated language barriers, it was perhaps surprising that patient communication, (although mentioned by three doctors) was not a major concern. Instead the interview data provided a strong narrative on inter-personal communication between practitioners, consequent difficulties with prescriptions and an air of inter-professional tensions, which will be discussed further in Section …[amber section removed from here and placed under Inter-professional considerations]

The data from this thesis has presented several opportunities to compare the identification of contributory factors from two different sources. A key finding is that interruptions and distractions while a relatively rare factor from the drug error report analysis, was far more prominent in the stage two data. This may be related to an

inclination to present written accounts in a particular style. In their sociology of the scientific discovery process Gilbert and Mulkay (1984) established a clear difference in content between written reports and interview data concerning exactly the same scientific processes. Their documentation portrayed a world firmly governed by scientific laws, where the scientist's actions are neutral. However, when interviewed, the scientists gave an alternative view of their various activities and judgements; admitting that their personal inclinations and social positions also exerted a tangible influence on the discovery process, adding that all sorts of variables impacted on their actions.

Although Gilbert & Mulkay's work might theoretically explain a difference in emphasis in interruptions across research methods, the reporting format in the traditional scheme also sent a specific message to those participating by asking that any text in the 'cause' box identified '*the* underlying cause'. Furthermore, as this box was routinely completed by the manager or equivalent, almost always removed from the immediate circumstances, they would be less likely to include error-producing conditions such as interruptions. The literature on interruptions as a contributory factor is quite compelling and like the factors previously discussed is a multi-disciplinary problem as demonstrated by the earlier systematic review. Furthermore, policy makers such as the Institute of Medicine have highlighted the phenomenon as a significant (Institute of Medicine 1999).

However, contrary to the above position, interruptions may serve a function. Miyata and Norman (1986) have explained that if interrupted, the human limitations in storing, retrieving and processing thoughts usually demands suspension of such processes; and recovering the current activity if a new one is introduced, is difficult. Task-driven processing is when a person devotes all of his activity to one task and is susceptible to recovery problems. Interrupt-driven processing, though, is seen in persons who have to constantly interact with others as part of their daily activities such as health professionals, and the different modes of processing can serve as a

function of both the person and the activity. Walji et al (2004) have actually argued that interruptions are critical cues in multi-tasked environments such as healthcare, and even promote productivity. To avoid interruptions being seen as an essential element of practice, Walji et al have identified three conditions for what might be termed effective interruptions. First the 'user' or person being interrupted must be interrupted at the right time, the task they are undertaking should not be spoilt as a consequence of interrupting, and the interrupt process should be carefully actioned to enhance its persuasiveness. However, a notable caveat is supplied by Tucker and Edmondson (2003) on the basis of their multi-centred observational studies, who have proposed that [ostensibly] resourceful and highly adaptable staff who normalise interruptions simply serve to hide away organisational weaknesses.

The interview data has exposed another interruption type. Categorised here as the social interruption, and rather like violations in comparison to slips, the social interruption is more likely to be deliberate (or intentional) being a psychosocial rather than cognitive factor. Interruptions require two parties. Of course the person being interrupted by a social question, as was the case in interview 1, may not wish to be interrupted. Their inability to say 'no, not now' may similarly hide away organisational weaknesses, but may also be strongly suggestive of a lack of error wisdom. It is clear from this data that interruptions are a cause for concern; it may also be that reporting, if carefully structured, may be one means of identifying their role in causation and their effects.

Knowledge deficit is well recognised as a contributory factor in the literature, particularly among doctors, but also nurses. In the categorisation process here it has been subsumed with inexperience largely because participants' accounts seldom differentiated between the two. Nevertheless, it is recognised that while inexperience can be a reason for knowledge deficit, a practitioner can be experienced in drug administration but not have the specific knowledge required for a specific drug regime, which could contribute to an error. While lack of knowledge

about a drug can be perceived as another individual-based factor, it has been categorised by Leape et al (1995) as both a 'proximal' systems factor (p.36), and in their search for 'third order whys' (p41) such as knowledge dissemination, as a systems failure. Conspicuously, Leape et al did not categorise inexperience as a factor nor make explicit whether it was part of their lack of knowledge category; however, the latter was defined as 'inadequate knowledge of indications for use'. In common with Leape et al, the participants here felt they and some of their colleagues were often short of imperative information and this was owing to deficiencies in pre-registration education. The pharmacists, who should be the most knowledgeable group ventilated the most concern, and not about themselves. Importantly, some nursing participants described how a lack of knowledge upstream [prescribing] allied to a lack of knowledge downstream [dispensing and administration] would lead to errors; rendering any 'defences in depth' (Reason 1997) porous, but added that although they may have inherited a prescriber's error, the accountability was shared. For the purposes of designing a reporting scheme, it would then seem appropriate to separate knowledge deficiency from inexperience, in common with the NCCMERP taxonomy. Additionally, mindful of participants' narratives, reporting schemes should clarify *through* reporting the precise stage where an error has occurred and assert that accurately identifying factors can necessitate a multi-disciplinary commitment to reporting – where doctors report prescribing errors even though they might manifest as administration errors.

Another factor almost entirely absent from the documentary analysis was faulty cognitive processes. The data demonstrated that busy practitioners inevitably engage in pre-packed solutions (Rasmussen & Jensen, 1974) often provoked by, for example, by patient or drug familiarity. Given the perceived climate of reporting, some practitioners might have felt uncomfortable in commenting on 'unsafe acts' (Reason1997) as they could have facilitated the inclination to individual blame that

is both expedient and fulfils convenient myths such as the just world hypothesis (Reason 1997, 2000). Yet they did, perhaps indicating that they too see unsafe acts as inevitable factors in the complex environment of healthcare (Parker & Lawton 2003). Therefore in conjunction with the findings here, they were included in the enhanced reporting scheme. Owing to the almost complete absence of this factor in the documentary analysis, and the interviewees' expressed wish for simplicity in any future scheme, it was decided to include, but also explain faulty cognitive processes in an accompanying guidance. Participants recognised that these faulty processes were more likely to occur in certain circumstances and be part of a concatenation of factors [e.g. when there are frequent interruptions], and that in nursing these would be more frequent for the more senior staff. This suggested that the future scheme should also prompt reporters to link their comments between circumstances and causes, having been reminded that a single cause would be less likely than multiple factors.

Inappropriate attitudes in medicines management, although described differently, have been identified in several studies, across the professions (Beso et al 2005, Dean et al 2002a, Taxis & Barber 2003, Tang et al 2007), and generally from qualitative studies. The exception was a questionnaire based study (Tang et al 2007) but this had been developed through staff focus groups, supporting the appropriateness of qualitative methods for seeking out the social phenomena argued to be so important in the aetiology of error (Dekker 2006). Dean et al (2002a) and Taxis & Barber (2003b) have respectively, developed quite strong arguments that a low value is ascribed to drug prescribing and administration. In this data set, there was intra-disciplinary and inter-disciplinary concern about sloppy attitudes to medication safety, but again participants did not speak of attitudinal problems in isolation from other factors. Indeed they were sometimes seen as the effect of working conditions and not simply a cause of error, once again clarifying, as does the literature, that a deterministic approach to error and its

resolution is inadequate. Some participants also perceived an inadequate degree of vigilance which they felt could be influenced by personality, but also seniority. This adds an extra dimension to the theoretical position that a senior's burden in carrying multiple schema can - due to the cognitive load - provoke error (Norman 1981, Reason 2000). Additionally, seniority may also lead to an inappropriately lax attitude. Furthermore, it was also felt that similar attitudes could foster rule violations. This again demonstrates that violations originate in psychosocial rather than cognitive factors but also that violations are factors in drug errors rather than drug error types – the latter having been mistakenly described as such elsewhere (Wheeler & Wheeler 2005). While this may seem pedantic, advancing the validity of any taxonomy of factors also demands separation of cause from effect. It is already known that there is rarely any intention to harm in violations (Parker & Lawton, 2003), and thus the reporting scheme while including violations as factors, would in the interests of encouraging reporting, steer clear of any prejudicial, pejorative language. In fact, some violations may in themselves be learning events. Nevertheless, the participants' comments on attitude, their concerns about defaulting cause to high workload, and the issue of social interruptions discussed earlier, may indicate that the position taken by Dean et al (2002a) and Taxis & Barber (2003b) warrants rather more attention for patient safety managers and researchers than has been previously given. Both propositions are further strengthened by the apparent diffusion of responsibility in double checking which is now addressed.

Double checking generated considerable comment. Four related sub-categories that essentially spoiled the process were evident: deference to authority, reduction of responsibility, auto-processing, and time dependency. Together they suggested double checking was a quite subjective activity where people form the principle components in a poor defence. Human error theory was influential in the analysis.

Deference to authority has been identified elsewhere as a key psycho-social

complication in double checking (Tamuz and Harrison 2006). Here, hierarchical problems were described in relation to rank, professional status and perceived mathematical ability. Consequently, even when incongruous data was fed into the checking process it was overshadowed by authority, suggesting that problematic double checking may be an important sign of the prevailing socio-cultural norms that still pervade the clinical setting and, for Leape & Berwick (2005) mitigate against movement towards becoming a high reliability organisation. The notion of reduced responsibility or complacency emanating from double checking is of course paradoxical, when the procedure itself exists to bolster safety promoting behaviours (Tamuz & Harrison 2006). It appears that staff meeting to check a medicine will also sometimes lead to a social exchange of the type discussed earlier. Interestingly in a mixed method study of Australian nurses who changed from double checking to single checking, that in the majority, it was found that an increased level of responsibility had emerged and prescriptions were checked more thoroughly (Jarman 2002).

Norman and Bobrow (1976) have identified how automatised procedures can be beneficial in high risk but stressful activities when operators default to well-practised repetition. Yet nine practitioners highlighted their concerns about the automatisation of double checking exacerbated by rote verbalisation, the pace of action, and giving the 'answer' in advance – often carried out in an environment packed with incoming sensory information. If double checking is to be improved, the ritualistic 'double checking chant' (Anderson & Webster 2001, p36), where the second checker simply repeats the words of the first must be avoided, furthermore it is thought that an over-reliance on double checking can lead to mindlessness (Tamuz and Harrison 2006).

It was also clear from ten participants that lack of time was a mitigating factor against even the most rudimentary double checking, and being time-poor also reduced the quality of checking by inadvertently leading to other problematic

behaviours such as auto-processing. Simply ceasing double checking in trying circumstances is likely to be counterproductive (Catlin 2004). It is argued here therefore that double checking be selective and that selectivity is based not simply on those medications which have historically always been double checked, but through a quick but careful assessment of those scenarios which harbour the greatest risk. This apparently problematic process demanded its inclusion as a factor in the reporting scheme.

The data on defences against error provided more detail into existing contributory factors as the discussion inevitably led to what was being defended against. The role of the clinical pharmacists as a source of expertise was seen as instrumental, especially by doctors; a role Shojania et al (2001) have classified as a patient safety practice with medium strength evidence of effectiveness. With greater relevance to this study, Crawford et al (2003) and Jones et al (2004) have shown practitioners believe that the increased availability of pharmacists also leads to more error reporting. It was also demonstrated that some doctors and pharmacists placed high value on effective cognitive processes, especially the ability to critically appraise the various processes in medicines management, which would in part overlap with the notion of error wisdom (Reason 2004). However, this view was largely absent from the nurses' narratives despite their recognition of problematic cognitive processes as a contributory factor. Reporting drug errors was not cited as a defence.

External co-rating is often too superficial to produce a meaningful analysis but a co-rating process can help gain an additional or alternative perspective on the data (Barbour 2001). In this study, the co-rater's blind review of six interview transcripts generated a similar range and lexicon of contributory factors as well as examples of reporting culture, but importantly also provided a different shade of meaning, as mentioned in the findings This was mostly concerning the author's conceptualisation of participants' contributory factors, [i.e. she understood and

described some factors differently]. This was probably because of her psychology rather than clinical background. Furthermore, although her perspective shared considerable theoretical ground with the Organisational Accident Model (Reason 1997), her ultimate research aim was to design a prospective error management tool drawing on the Tripod Delta model (Hudson et al 1994). Consequently, her perspective was very pragmatic, re-focussing this analysis on the structure of the enhanced reporting scheme - itself an error management tool.

10.2.3 Reporting culture

The difference between reporting rates across specialties, identified in the stage one data, is potentially a safety alert in itself. The measure applied, albeit crude, demonstrated a reporting rate that was three times higher in paediatrics than medical and elderly care. This may have simply been due to the complexity of pharmacological interventions and dosage calculations in paediatrics (Simpson et al 2004, Kaushal et al, 2001); alternatively, it may indicate a raised staff awareness of the lower threshold for harm after a drug error. Thirdly, the differential may be attributable to a reduced tolerance of patient safety violations in particular units (Shaw et al 2005), allied to a more open and supportive culture (Giles et al 2006).
The free text analysis from the stage one data confirmed that some reports could be:

- Superficial
- Arbitrary
- Lacking logic in their process
- Adapted due to procedural limitations
- Influenced in style and process by the particular professionals involved
- Pejorative with minimal rationale for action taken

The lack of specific information here compromised the understanding of drug errors and their causes but it was possible to analyse reporting as a means of

communication and some of the inherent values. In this paper-based system, which utilized the three stage model of circumstances, cause, and action taken, it was clear that even when practitioners were able to elucidate an adequate description of circumstances, the contributory factors were not consistently identifiable. In addition, 33.8% of the reports were defined as brief. These reports were lacking information, misidentified the cause as the error, or sometimes involved – usually without clear justification – a degree of blame for the protagonist. The content of those reports, where either the contributory factors were absent, or the error was seen as the cause, can be interpreted using the work of Woods and Cook (2003) – whose summary of the assumptions behind human error theory collectively known as the 'New Look' was described in Chapter 2. Woods and Cook have explained that the term error is not employed in the daily discourse of health professionals. When a contributory factor is absent, Woods and Cook, in common with Scott's assertion that everyday routines are often dominated by organisational requirements, suggest that the decision to sign off the report is often an indicator of the manager's belief that a sufficient understanding of the situation has been reached (Scott 1990). While this may also be an indicator of the manager's lack of expertise in risk, this implicit decision-making is very likely to limit any potential learning.

Error as cause assumes that the incident was simply due to human failure, it propagates the myth that risk management protects the public from erring and incompetent practitioners. It contradicts Rasmussen's developmental thesis that knowledge and error emanate from the same mental sources, and only success differentiates the two - success and failure are both perfectly natural phenomena. In common with the absent factor phenomenon, any learning potential is foreclosed – error becomes the final outcome and not a potential sign of systematic failure.

It has also been argued that attributing causation to systems is more arduous than blaming an individual (Merry 1995, Reason, 2000), a systems overhaul also costing

considerably more than the isolation of an individual, especially if they are seen to be culpable. Additionally, any perceived 'performance deficit', to use the NCCMERP lexicon, particularly if the protagonist is the last link in the error chain due to a moment of inattention, is likely to gain more attention than the less obvious systems failures. The documentary analysis here suggests this could be more prevalent in nursing than medicine or pharmacy. Nurses are of course the last link in the chain prior to the patient which inadvertently leads to them inheriting both prescribing and dispensing errors; but as a professional culture, they might also be more inclined to blame. In her exploration of group and organizational factors in drug administration errors, Edmondson (1996) has proposed that the more hierarchical the structures the more exacerbated the blame, and as a consequence, reporting becomes more difficult. Thus, one might expect those organisations or their subdivisions with the highest reporting rates would also have the more detailed reports. In fact such a proposition could be made concerning the research Trust's neonatal unit, which submitted by far the most reports per ward (115 compared to 67 from the second most prolific reporting ward), the associated quality of which in many cases, was demonstrated in Chapter 6. In the contrasting brief reports which were generally those that singled out individuals in the action taken, there was ironically, no evidence of a slip, lapse or mistake that could - at least theoretically - isolate the protagonist. There is however, another more obvious rationale for the brief report – the ways of working and intrinsic 'production' pressures in modern hospitals simply demand a quick fix (Edmondson 2004, p3).

The interview data specific to evaluating the existing system also served to provide an additional insight into the participants' culture of reporting. Although a more enlightened approach to error was acknowledged by some, there was an overwhelming sense that the existing process disenfranchised the reporter and consequently, there was little learning. Furthermore, the nurses collectively put forward an arresting argument that the 'upward trajectory' of action taken, often

focussed on individuals – resulted in blame – in line with the findings from the documentary analysis. An apposite comment came from the junior doctor and ex-nurse, mindful of the consequences she had witnessed for those of her nursing colleagues who had reported errors, she basically proposed that unless there was patient harm, there was no real point in reporting. For patient safety policy makers this flies in the face of the policy reporting agenda.

For the most part, then, a blame culture was seen to persist, and as commented upon in the findings, appeared unavoidable, and even though the literature galvanised the view that blame is an inevitable consequence of reporting, it is questionable as to whether blame has become something of a self-fulfilling prophecy. While blame may be less of an issue in the medical profession, the inter-professional concern that doctors exhibit for nurses, and their view of reporting as a means of settling scores, should not be ignored. The proposition that nurses might, through an individual focus, find themselves perpetuating blame (Hand & Barber 1999) should not be ignored. The preceding documentary analysis, may support this view which suggested individual reprimands were more likely, especially in nursing and ironically when evidence of causation was at its weakest. The stark lesson for the enhanced reporting scheme was to make sure any guidance for reporters squarely acknowledged the central principle of human error: that errors arise from what is often a complex amalgam of human fallibility, local conditions and systems failures. Additionally, more detail should be sought from reporters. Furthermore, although drug error is quintessentially a multi-disciplinary problem, it would seem that reporting is generally *not* a multi-disciplinary initiative.

Miller et al (2006) have argued that nurses and pharmacists are perfectly positioned to detect and report errors yet, not untypically, the authors ignored medical staff, who also appeared here as outliers in the reporting process. Indeed, Dejong et al (1998) in constructing their drug error reporting scheme, did not involve medical staff at any stage, a salutary thought despite knowing the

epidemiology of drug errors demonstrates prescribing errors to be a leading source of adverse drug events. Two messages were evident for this study. First, that a sense of fair play as well as objectivity is made explicit in any proposed reporting scheme and secondly, that the multi-disciplinary nature of drug error is recognised both in the planning and implementation phase.

The participants' combined and consistent portrayal of drug error reporting as a thankless treadmill re-illuminated the various barriers to effective reporting as identified in the literature. The perceived impotence in providing organisational, and in some areas, local feedback was predominant – again in line with the literature (Dejong et al 1998, Walker & Lowe 1998, Wakefield et al 1999b, McArdle et al 2003, NAO 1995, Waring 2005, Evans et al 2006). The nurses used their often emotive language to convey considerable under confidence in what they perceived as a cumbersome and often punitive process. The doctors broadly concurred and although this avenue of inquiry again revealed that many believed reporting was generally the domain of nurses, they felt that reporting would be better if managed locally rather than organisationally. In line with this, but also displaying their general dislike of record keeping, verbal communication was seen as preferable to written communication to protect collegiality and apropos, advance learning. This however, neglects organisation-wide learning, enhanced by human error theory (Parker & Lawton 2006) and seen as a leading priority by key policy makers (DoH 2000a, Agency for Healthcare Research & Quality 2003, WHO 2006) owing to its relevance, in for example, improving safety at clinical inter-faces. All of the pharmacists and their technician colleagues unconditionally valued the detection of drug errors, but many felt the process of reporting actually interfered with, rather than complemented their work. What is more, they believed they could not report all they detected, and if they did they were concerned about how such a volume of data be analysed. This probably accounted for their practice of using a pharmacy-managed regional scheme (although its quality of feedback is unknown

to the author) and their method of formally reporting all prescribing errors for just one month each year. Miller et al have suggested the analysis problem is not as big as foreseen, as long as clear error definitions are employed and within a multi-professional integrated data base (Tamuz et al 2004). However, these views were based on an electronic scheme.

Lack of feedback then became a major driving force for the enhanced scheme in that feedback would be made an explicit and mandatory part of any action taken; extolling an educational approach and shown to be a successful way of reducing reporter concerns in documenting their fallibilities (Potylycki et al 2006). As pace of feedback is hastened by an electronic medium (Miller et al 2006), it was also decided the enhanced scheme would be designed to allow easy conversion from a paper scheme to electronic. Carthey (2001) has acknowledged the importance of a vibrant safety culture in facilitating reporting, it would seem that ineffective reporting may be a hurdle to facilitating such a culture.

10.2.4 Inter-professional differences

The rates of reporting by profession calculated from the stage one data showed a strong symmetry with the first report from the NPSA's National Reporting and Learning System which showed that 73% of their received reports were from nurses and 7% from doctors (Vere-Jones, 2005). Several other studies concerning generic errors (O'Neill 1993, Stanhope et al 1999, Kivlahan et al 2002, Uribe et al 2002, Lawton & Parker 2002, Tuttle et al 2004, Nakjima et al 2005, Evans et al 2006, Miller et al 2006, Evans et al 2007) and medication errors (Wilson et al 1998, Furokawa et al 2000, Ashcroft et al 2003) further support this trend as identified in Chapters 2 and 3. Even when the figures are expressed as a percentage of their respective professional populations, nurses reported far more frequently than doctors; a figure that is presumably inflated by nurses being the principle interceptors of doctor's prescribing errors (Leape et al 1995), although pharmacists

might dispute this. The reluctance of medical staff to engage in reporting activity, especially junior doctors, may be a generic issue. Daniels & Marlow (2005) have documented that even in relation to self-injury, whilst surgeons suffer the most needle stick injuries they were least likely amongst health professionals to report them. Although largely unrelated to error, the reasons put forward by Daniels and Marlow included time constraints, lack of knowledge about reporting and concerns about confidentiality.

The stage one data also suggested that error knowledge might be produced in particular ways. Although this was sometimes unit-specific, it was often profession-specific; similar types of events could appeared to foster contrasting narrative styles which led to different actions. Nurses, as mentioned earlier, were often emotive in their response to an error, self-deprecating, and as a professional group appeared more inclined to blame. In contrast doctors, if they did report, were often less emotive and tended to be self-*advocating*, the latter perhaps reflecting how the particular management systems surrounding them responded. In the nurse-initiated reports, knowledge was then produced that offered action for problems before accurately identifying the problems themselves. Ironically then, although doctors submitted very few reports relative to nurses, their management of a reported error was, at least ostensibly, disinclined to focus on human failure.

Carroll & Quijada (2004) have claimed that hospitals are not single cultures but an assortment of subcultures divided by profession, speciality and department. Here, participants in the qualitative interviews revealed a number of different orientations to error supporting this claim. These orientations appeared to differ by discipline and by unit, not unlike the differences in the report data. Although these remain cautious propositions, there was also evidence of differences in both reporting rate and style along similar lines, reflecting the preceding incident report analysis. In fact a picture emerged of nurses responding to error through avid reporting,

appearing motivated by the belief that this was a mandatory requirement, but aware that the response would likely involve some form of reprimand. Importantly however, the interviews occurring as they did after the documentary analysis also revealed a surprisingly discerning approach to error across the professions, their understanding of causation and concatenation being quite obvious. This confirmed that the enhanced reporting scheme, and any staff preparation, should aim to provoke such knowledge. The author was though, aware that the way in which the interview participants were recruited could have produced a sample that held more knowledge of drug errors than their non-volunteering peers.

There were further commonalities between the interview responses of the participants by profession and their error reports, although the conclusions drawn are rather more tentative. There was a much greater self assuredness in the doctor's remarks across their grades. They projected a rational view of infallibility, and as they did not comment on any known experiences of disciplinary action, and their rationality was most probably reinforced by the behaviour of their seniors when an error was identified. The pharmacists exhibited a similar level of confidence and although some were highly critical of the attitudes of their medical and nursing colleagues towards drug errors, they were clearly orientated to a systems perspective. It was especially difficult to gauge the comparison between the written reports submitted by the pharmacy staff and the interview data as they largely used a profession-specific regional reporting scheme in preference to the trust scheme. Nevertheless the data gave an early sign that the multi-disciplinary sample yielded three interesting professional archetypes, each of which were instrumental in delivering drugs to patients, and each of which had both different and shared concerns about drug errors.

This particular category was in fact replete with quite strong opinions, although those giving such opinions, unlike Interviewee 12 whose text appeared suggestive of a negative case, did not routinely engage in polemical arguments. Here, the

topic of reporting while giving rise to some weighty assumptions, for example, 'most doctors' opinions is that nurses love them' (36D), largely showed that the doctors here felt considerable sympathy for their nursing counterparts. The pharmacists interviewed in this study were, interestingly, less understanding of their other professional colleagues. Their narratives disclosed tensions about nurses failing to understand the workings of a pharmacy department, the sometimes chaotic nature of 'ward practice' so graphically described by some of the participants here, and as discussed previously, that their unflinching focus on individuals would inevitably result in blame. Mindful of the undoubtedly important relationship between pharmacists and nurses in detecting errors throughout the delivery process, future research might more fully analyse any common stressors in their relationship, and also how their combined working might inform preventative measures. As it appears a more group-orientated culture may relate to a perceived higher level of reporting (Wakefield et al 2001), although based on a study of nurses, it surely has broader application; a lack of attention to such relationships may be a lost learning opportunity.

There was a sense from some interview participants that medical staff did not like 'writing stuff' (16N). While this may again confirm the general lack of enthusiasm for record keeping discussed earlier; it may also confirm that doctors have a certain freedom somewhat reminiscent of the so called 'Atlantic barons', the pilots who, before Crew Resource Management, did largely as they wished, regardless of other crew members (Johnson 2001). The orthopaedic surgeons referred to by the senior nurse (23SN) appeared to possess a particularly potent freedom which impacted on their junior [medical] staff who apparently could not modify a consultant prescription on the basis of it been incorrect. This phenomenon was independently corroborated by the surgical pharmacist in very stark terms, and from a neighbouring surgical unit by an especially direct senior house officer (26D) who used a vivid example to demonstrate the junior doctor's 'timidity'. Criticism of

nurses' and pharmacists' inter-professional communication by doctors was noticeably absent, this fitting with a large survey of critical care teams conducted by Thomas et al (2003) where doctors were generally satisfied with their nurse interactions but the nurses in turn, expressed various difficulties with status differences and related, unresolved problems. In contrast, again supporting the theory that quite different attitudes to safety rest on particular subcultures, a consultant and one of his juniors were quite self-effacing about their prescribing, avoiding a focus on individuals and instead focussing on how chart design might threaten effective written communication, reflecting the maxim that systems design is a central principle in safety improvement (Reason 1997).

Turner (1992) has eloquently documented the rigid hierarchies within which the healthcare professions exist; both pharmacists and nurses having historically for a whole host of reasons, remained subservient to medicine. Almost 30 years ago, Bosk (1979) elucidated the omnipotence of senior surgeons in his qualitative study of medical failure, and the various ways in which they maintained rank authority. It is not the intention here to advance the sociological critique of status and power between health professions but to reconsider the impact of dysfunctional communication and communication systems on drug errors. It would nevertheless seem that despite a significant emphasis being placed on erasing traditional professional demarcations and promoting egalitarianism through the NHS Plan (2000b), there is some distance to travel. Crew resource management has allowed the aviation industry to improve the quality of interactions between crew in admitting mistakes and adhering to safety policies, as well as improving incident reporting at an acute hospital trust (Higton 2006). However, comparatively substantial advances in team working in what is argued here to be a rather different culture, may be more challenging.

10.2.5 The organisational and societal context

As pointed out on page 144, half of the reports analysed by the author in stage one

of the study were also reviewed by another qualitative researcher. Although his contribution was modest, and took place towards the end of the author's analysis when the author's perspective was well formed, his review posed two interesting questions which have added weight to two tracks of discussion: 'who is the expert in the incident or error?' and 'whose reality is being portrayed in the reports?' The two questions can be related.

The 'action taken' did not consistently acknowledge the influence of unsafe acts, local factors, and latent conditions - seen to be instrumental in the aetiology of errors (Reason, 1990) – but for most practitioners it would seem to be a relatively foreign concept, even in lay terminology. The illogical relationship sometimes seen between circumstances and cause may have been exacerbated by the organisational process of allocating more senior or management grades, who were almost always distal to the circumstances of the error, to identify causation. While this is another lost opportunity to gain valuable contextual information concerning cause, the merits of which have been demonstrated by Runciman (1993), this also shifts the expertise from those at the 'sharp end' (Reason 1997, p10, Reason 2000, p768) to management. In common with other studies cited in Chapter 2 (e.g. p.53), there was a reluctance on behalf of some practitioners to submit reports due to a lack of trust in management – perhaps epitomised by the belief that reporting should be confidential therefore implying the need for protection from management (Berman & Collier 1996). Failing to acknowledge the potential expertise of the reporter's position may answer one of the above questions. An organisation's perspective is often expressed through its documentation (Scott, 1990) – one might then conclude here that the protagonist is *not* seen as having expertise.

This supports the epistemological position taken for this study, that the free text in the incident reports were interpreted as social facts (Atkinson & Coffey 1997:47) but not literal representations of reality. In fact there appear to be at least two representations of reality – those of the managed and those of the manager – their

alternative constructions being influenced by competing values and demands. However, the control exerted by management in attributing causation – especially if based on the superficial data discussed above could have quite pernicious implications. In analysing the features of institutional documents, Prior (2004) has argued that documents can establish the realm and expertise of the parties involved, but can also consolidate the identities of the individuals involved.

Interestingly, the free text of error reports has actually been vaunted as a key source of safety information (Runciman 1993, Billings 1998a, 1998b) but its actual weaknesses may be more useful to researchers (and risk managers) than might initially appear, especially if subjected to an analysis similar to that employed here. If it is accepted that the free text is a social product of the organization, it may also provide valuable information about individual, local and organizational responses to error; in fact variations in reporting have been thought to be more closely related to incentives and local culture than quality of health care (Cullen, 1995). Here, the lack of a clear relationship between causation and action taken seemed to render blame more likely; even though as Runciman (2003a, p976) has argued, 'outcome is a poor index of blameworthiness.' Free text may then be a marker of how well the reporters and their managers understand error, its causes and its effects.

Errors arise from complex roots. It is acknowledged by the National Patient Safety Agency that targeting systems should take precedence over taking action against individuals, and human perfection is a myth (NPSA 2004). However, the claims made against the data here intimate that in spite of, or perhaps even due to, the complexity of error and its often unpredictable causes, organisations may inadvertently default to myth. The content analysis employed in this study, together with the 'New Look' referred to in Chapter 2, can offer an explanation of how error can be inappropriately interpreted.

The methods chosen to collect and analyse the stage one data allowed a detailed

examination of the way in which drug errors, their contributory factors and any action taken were presented in one institution's incident reporting scheme. The drug error reporting process was dissected to expose its key characteristics as a means of organisational communication, from the reporter's written submission to the eventual consequences. The lack of contributory factors in a substantial proportion of the reports – particularly in relation to certain error types – has clear implications for risk assessment and resolution without further data collection. However, there were gaps in the data. Little knowledge existed on the antecedents of reporting, [i.e. *what motivates reporters to report*]. Thus the stage one data analysis directly informed the development of an interview schedule for stage two - the qualitative interviews - but also served as rationale for engaging directly with reporters.

The findings here also bear societal implications. Catastrophic drug errors such as that which resulted in the death Theresa Innes have a far reaching impact on society as well as the host organisation. The public response is undoubtedly influenced by often intensive media coverage (e.g. Bale, J. in The Times March 21st 2006), and although organisations may choose to adopt a learning rather than blame approach to their staff following an error, the public may be less sympathetic to the profession and their organisation. This is borne out to some extent by Robinson et al (2002) in a large survey of doctors and public in Colorado who found that there is palpable concern among the public about error and there is support for mandatory reporting (see page 34). Whether public pressure will have a lasting, widespread impact on the priority battle between production and safety outlined above, remains to be seen.

10.3 Mini-piloting of the enhanced reporting scheme

10.3.1 Practical considerations

To allow early discussion with the trust's senior management team on the

development of an enhanced reporting scheme, Ritchie and Spencer's Framework model guided this first part of the analysis where there was a purposeful search for specific data on: the nature of reporting at that time, patterns, barriers, expectations, and suggested modifications (Ritchie & Spencer 1994). Therefore the stage two data is first discussed with reference to the implications for the actual reporting process. The most sweeping implication, based on a clear majority (65%) of participants' views was to separate the reporting of drug errors from the mainstream incident reporting scheme; a position supported by the lack of drug specific detail in the stage one data. Indeed the traditional reporting format, owing to its generic nature and paper-based format, could not accommodate specialist prompts [e.g. drug error type] – something many participants were keen to adopt. Furthermore, the systematic review of drug error reporting included eight reporting scheme evaluations, all of which were based on dedicated drug error reporting schemes and although their data sometimes lacked penetrative depth, they did provide a platform for specialist analysis. Notably, the one scheme which had also been subjected to an additional evaluation when generic, was redesigned as a specialist scheme before the study proper (Dejong et al 1998).

As alluded to above, the majority of participants also expressed a preference for tick boxes to identify error types, but also contributory factors. The AIMS has used this approach almost since its inception (Webb 1993), and despite incurring the perennial problems of poor medical staff compliance and maintaining senior staff motivation (Evans et al 2006), the AIMS group have generated one of the most utilitarian incident reporting data bases in existence (Vincent 2006). Additionally, electronic schemes such as that described by Tuttle et al (2004) in Chapter 2 have adopted the same, Tuttle et al providing an important message for the effective transition of a paper-based scheme to an electronic one. Many of the participants also however, maintained that the free text should be kept, the value of which has been demonstrated by Runciman (1993). There was also a strong desire for

simplicity, which suggested that the way in which error types and contributory factors were presented would have to be understandable to reporters. This would have implications for the way in which the principles of human error theory might be integrated into the scheme.

As has been previously explained, the Stage one data demonstrated an absence of contributory factors in 27.8% of reports and a lack of pertinent detail in many others. Aware that the commentary on causation in the existing scheme was completed by the protagonist's (or reporter's) manager or equivalent, participants were asked who should record contributory factors. Also, based on the Stage one data, there appeared to be a distinct lack of logic between causation and action taken – even though both were mostly completed by the same person. It was clear that the vast majority of participants believed the protagonist should play a role in recording the contributory factors; however facilitating the option for both manager and protagonist to do this in a paper-based scheme created an overly complex format which was discussed at the relevant trust committees but not accepted. The scheme was then enhanced by allowing the reporter to identify causation, supported by the argument that blame is more likely to be apportioned by someone when s/he is not involved in the event under scrutiny (Caplan et al 1991), and that reporting should be a prime opportunity to actively engage health professionals *en masse* in safety activities. This change was also predicated on the belief that the logic between circumstances and causation would be improved.

Finally, evidence from the literature demonstrated that lack of feedback was a key motivational barrier to reporting across the professions (Dejong et al 1998, Walker & Lowe 1998, Wakefield et al 1999b, McArdle et al 2003, National Audit Office 1995, Waring 2005, Evans et al 2006) – especially in paper-based schemes (Miller et al 2006). The participants in this study, across the professional groups, expressed similar views but allied to a desire to resolve concerns locally, and as in the literature reviews especially among the medical staff. Encouraging local action

would also be a means of reducing the organisational difficulty of giving feedback in a climate where reporting rates, continue to rise. This trend is also apparent in the NPSA's National Reporting and Learning System which has now received over one million incident reports since its inception in 2003 (Scobie, 2007), which demands considerable analysis (Armitage & Chapman 2007). Consequently, it was decided to also prompt managers charged with taking action, offering them the options of one to one, local unit, and if seen to be of special educational value – organisational feedback. Additionally and in line with human error theory, a range of actions were offered including interpersonal support, education/training, supervision, and systems change.

The principal differences between the enhanced scheme and its predecessor were the inclusion of guidance; structured cues for data entry; an evidence based list of contributory factors which could be selected and scored in importance, and by the reporter rather than their manage or senior; and structured cues for action taken. This section begins with some reflections on the piloting process.

10.3.2 Piloting process

It has been demonstrated that although drug errors are a multi-disciplinary problem, reporting is not a multi-disciplinary process. Knowing this, staff training for the mini-pilot demanded attendance at both profession-specific and multi-professional divisional and unit meetings. Nevertheless, it can be seen from the Stage three findings, that nurses remained as they had previously, the most common reporters. The findings also showed that it can be difficult increasing detail in the free text boxes despite training and written guidance being introduced and made accessible to all reporters as part of the reporting ledger. The comments of Cullen et al (1995) on the difficulties of instilling enthusiasm in reporters even following a significant training programme are apposite. The training process was time consuming, and although largely carried out by the author should send a clear signal to those implementing future training programmes - introducing a modified reporting scheme

necessitates behavioural and inevitably, some cultural change – which in the health services can be especially taxing (Lewis & Fletcher 2005). From the author's experience, it would also seem that training and especially raising staff understanding of error and their causation, is a critical component in increasing the quality of reporting, and not simply the design of a reporting scheme. The challenge is perhaps exacerbated by the notion that patient safety learning is about:

'….putting our failures in the open and our humility to the test' (Howe 2006, p196)

Re-reading the guidance (Appendix item 17) as a reporter rather than a researcher reminded the author that Howe's comments were particularly applicable here. Furthermore, if reporting schemes like this are to capture the faulty cognitive processes that are often a part of human error, it means for example, nurses and pharmacists asking doctors to report their own prescribing errors rather than the vicarious process previously elucidated, necessitating a level of co-operation across professional boundaries seen by Berwick and Nolan (1998) as an essential pre-requisite in safety improvements. A longer piloting process than here, allied to a user evaluation is then needed to confidently elucidate changes related to the above but also to establish how such change was perceived and experienced.

10.3.3 Quantitative findings

This section will consider:

- Reporting rate
- Professional differences
- Timing of errors
- Stage at which error occurred
- Classification of errors
- Contributory factors
- Action taken

The total reporting rate (count of reports submitted from all units) was highest in the

first four weeks of the mini-pilot, 26 of the 49 reports having been received in that time. This perhaps reflected what appears to be a common phenomenon where, following the introduction of new intervention, there is some diffusion of effect as any initial motivation from training begins to diminish. If this was as a consequence of problems with completion and or submission of the report – something not explored as part of this mini-pilot – process changes or further training might be considered. Despite the overall downward trend in reporting over the three months, all the reported errors were near misses – an error outcome consistently less likely to be reported than an adverse event (Lawton & Parker 2002, Taylor et al 2004, National Audit Office 2005, Evans et al 2006).

Reporting scheme evaluations have rarely considered reporting rates across clinical units within one organisation, although Desikan et al (2004) did measure this, and found surgery to be the most prolific reporting unit in one of two schemes. This was though, a pharmacist-only, rather than a multi-disciplinary scheme. The statistically significant rise in *multi-disciplinary* reporting in the surgical units here was encouraging. However, the relative fall in reporting in the neonatal unit should not necessarily be inferred as problematic. Staff have obviously reported errors, and more frequently than their departmental peers, but they may have had to expound more effort in using the new scheme or simply may have not experienced as many errors in the mini-pilot period. Furthermore, although not included in this thesis, the inter-unit differences in reporting could have been analysed using one of the various denominators discussed in the epidemiology of drug errors (Chapter 3) to more accurately contextualise the rates [e.g. against number of prescription items], and also increase the validity of this measure.

Professional differences in reporting persisted. Again, the comparative reporting rates of doctors and nurses, showed that despite nurses being the predominant reporters, they were not the leading protagonists. This finding further substantiates the evidence from the literature and empirical findings here that medical staff are

reluctant reporters, and that pharmacists despite their instrumental role in detecting errors, were not commonly reporting in this trust (due to the reasons given earlier). However, both doctors and pharmacists submitted reports to the mini-pilot scheme and at a higher rate than any of the other three month comparative periods chosen. It is also likely that although the training of staff pre-pilot was a multi-disciplinary initiative; in order to consistently increase reporting rates, the other constituents in advancing patient safety such as effective leadership and a tangible, organisational commitment to safety (Leape, 2004) are essential.

The timing of errors showed a peak at the lunchtime period, and the bulk of these errors involved administration. This data was not displayed in the stage 1 findings due to missing and inaccurate data. However, a limited analysis showed some commonality in trend. There were far fewer reported errors at night which has been seen elsewhere and is thought to be due to reduced patient activity (Selbst et al 1999). A key message for analysis of time data is to clarify that the time recorded by reporters is the time of the error rather than the time of reporting. Secondly, if there is then a clustering of errors around a particular time, a review of organisational systems might be necessary as an unpublished audit of drug errors in another comparable trust (Clift, 2007) has shown that unsafe acts have proliferated when peaks of activity have occurred, including mental slips stemming from interruptions. There is also some evidence that error type can differ by time; day time errors being more likely to involve wrong drug, wrong dose, and night time errors more likely to involve wrong time or route (Allen & Barker 1990). In this study, only four errors occurred after 22.00 hours and before 06.00 for which there was no dominant error type.

One of the goals of the scheme was to provide new information. Having data on the stage of drug delivery where the error occurred allows reporters to formally document the source of the error. More importantly however, this might then reduce the often inappropriately singular emphasis on administration errors, evident

in the stage one and two data, which have actually stemmed from prescribing (and sometimes dispensing) errors. This should also remind unit and risk managers to analyse failures in the entire drug delivery processes - seen as imperative in risk reduction (DoH 2004, p53).

It is contended that a further improvement was apparent in the number of definitive drug errors reported (according to the NCCMERP taxonomy), a definition included in the reporter's guidance. The Stage one data showed that 79% of what were apparently classified by the trust's risk management department as drug errors were in fact definitive errors. Whereas, in the mini-pilot scheme, three errors were not judged as drug errors by the reporters and three by the author, (however, only one of these was mutually agreed by both parties). Increasing the proportion of definitive drug errors should facilitate easier and more accurate coding, and lead to improved measurement and analysis (Walshe 2000). Secondly that the definition used is the one preferred by the Department of Health and NPSA is a small step in stemming the plethora of terms already known to confuse the field (Rubin et al 2003, Yu et al 2005). It is also argued that providing this type of information to reporters and managers is a free lesson in risk management. On a less optimistic note, four reporters having not confirmed the incident was an error, and a further four having judged by the author to have insufficient data to define the incident, suggests a review of the form design may be helpful. It may also indicate the need for improved training. Weaknesses of this nature in form design might be overcome by electronic reporting where sections have built in alerts if data input is incomplete, also combating some of the errors that are actually introduced by IT systems themselves (Ash et al 2004).

The reporter's classification of the error outcome (near miss or adverse event) was also collected, mindful that the reporter had again been supplied with the relevant definitions. The author then analysed each of the reports in full to reach his own verdict on outcome. In view of the notable variation between reporter and author,

an independent review was carried out. The subsequent 100% agreement between author and independent reviewer may again indicate reporter difficulty with interpretation. It was apparent in training that some staff were especially unfamiliar with the one of the Department of Health's two definitive types of near miss - where the patient actually *receives* the drug incorrectly but there is no harm (DoH 2004, p21). The single report in which the reporter apparently judged the drug errors as having led to an adverse event had also decided to tick the near miss box, as well as ticking each of the contributory factors as been present. Inappropriate interpretation may go some way to explaining such variation, and may also account for some of the inappropriately blank entries. However, reflection on form design suggests the term 'drug error' as a yes/no option in Box seven was unnecessary and may have contributed to confusion with the near miss tick box immediately below. This finding is also a valuable reminder that as Thomas et al (2002) have demonstrated, subjectivity in interpretation cannot be eradicated.

Amalgamation of all the dosing errors under one heading made this the most prevalent error type, which has considerable parity with a range of other studies (Bates et al 1995a, Bates et al 1995b, Lesar et al 1990, 1997) which used different methods. However, it should be stressed that Lesar et al's studies were only based on prescribing errors. Wrong drug and drug omission errors were respectively, the second and third most common error types. Drug omission has again been seen to be a common error type (Ridge et al 1995, Ho et al 1997, Dobrzanski et al 2002), but wrong drug less so. Drug error types had been extrapolated from the stage 1 data but with considerable difficulty, despite its importance in the epidemiology of drug errors.

The stage one findings suggested it was imperative to have a list of contributory factors, and as all reports here except one identified contributory factors, it is seen as a notable improvement. Interruptions and workload were predominant alongside communication difficulties, adding further support to the position of the

stage two interview participants, and in line with the systematic review. The arguments as to why such error-producing conditions might be a prevalent factor for practitioners have been well rehearsed earlier in this chapter and, and in what is essentially a rating scale, their choice of factors could also be suggestive of the recognised halo effect (Oppenheim 1992), exacerbated by their previous experiences of reporting. Factors such as interruptions are then controversial – they may relate to problematic or inappropriate ways of working but they might also be symptomatic of what Reason refers to as 'resident pathogens'. These pathogens can be the precursors, in combination with other factors and the chance alignment of porous defences, of catastrophic incidents. The message for reporters and managers is reflective of the central purpose of the scheme, it is the task of both parties to assess and describe the nature of the factors reported, any relationship with other factors that might give rise to an error, the eventual error type, and its outcome.

Reporters did not cite any other factors in the supplementary text box (bottom of Box 11), possibly indicating that the list of factors provided had some face validity, and through their theoretical underpinning, construct validity. Although Bates et al (1999) found that patient factors in ADEs were of minimal importance, the analysis of free text in Box 8 (Circumstances) did sometimes allude to patients [e.g. giving incorrect prescription data to staff], which may suggest the future inclusion of 'the patient' as a contributory factor. Interestingly, 17 of the 19 contributory factors listed on the report were cited in the 46 definitive drug error reports containing factors, and 28 (60%) had more than one factor ticked which might be indicative of the notion of concatenation (Reason 1990), but should also be indicative of a greater analysis by reporters.

The ordinal rating scale for contributory factors, although easy to use and to be found in other reporting schemes for rating the impact of an error (Tuttle et al 2004), may be problematic in untutored hands (Oppenheim, 1992). Inter-rater

reliability can be poor, although inter-rater reliability could not be measured with real time errors unless a simulation study was mounted. While the problem may have been eased here by only having one concept to rate against a range of variables ('importance of the factor'), the results did again, suggest some problems with interpretation.

The commonly documented disinclination to use extremes (or error of central tendency) was not evident, instead there was a bimodal distribution (table 9.12) possibly suggesting that a reporters' natural inclination might be to either simply score a factor as present, through indiscriminately giving a score of either 1 or 10. Reason (1997) has also commented on the problems with rating scales and error, reporters who are critical of the organisation, will use the scale to vent their personal frustrations and those taking the opposite view will be unrealistically accepting and lack an analytic approach. Reason's proposed solution is to gather as much data as possible to create an average. The median was used here to address the skewing, again shown in table 9.12, the inter-quartile range has been included to clarify distribution around the median. Considering the sample size, there was little effect other than reducing the ranking order of interruptions, and raising that of arithmetical error. The results may suggest narrowing the scale to 5 items thereby giving reporters a less diffuse rating scale.

The choices for 'Action taken' were, for the purpose of analysis spilt into immediate action, and feedback action. The 38 responses were not of course mutually exclusive, managers having the option of ticking as many boxes as they would view applicable. Few conclusions can be drawn from the mini-pilot other than the data suggesting feedback to the person closest to the error in 22 (57%) of the reports, was, unlike the existing scheme, implemented and documented. Aware that a key barrier to reporting is lack of feedback as previously discussed (Dejong et al 1998, Walker & Lowe 1998, Wakefield et al 1999b, McArdle et al 2003, NAO 1995, Waring 2005, Evans et al 2006), and that it is even viewed as a contributory factor

in drug errors (Leape et al 1995, Sanghera et al 2007,) this is encouraging. However, the quality of feedback rests on a robust analysis (Barach and Small 2000), and therefore it was equally encouraging to see a stronger and joint analysis, in tandem with more focused feedback. A snag however was that not all reporters were privileged to see the manager's response - a clear drawback of a paper-based scheme. This could of course be eradicated by an electronic scheme where all those who have contributed to the report can gain access to the information recorded, as in the airline industry (Last 2004). Even though this scheme was based on multi-disciplinary data, it was, other than in the units identified as having a multi-disciplinary ethos, introduced into a reporting *system* which was managed *by discipline.* A further benefit of electronic reporting would be the potential advantage of sharing lessons learned across disciplinary boundaries – particularly as electronic reporting seems more popular than paper reporting with medical staff.

10.3.4 Qualitative findings (free text analysis)

There was more comprehensive coverage of the circumstances around drug error, but despite written guidance being available as part of the reporting process, some free text was so brief as to render any contextual detail impossible. It is possible that the availability of a contributory factors list may have suggested to reporters that causation could be addressed sufficiently without recourse to writing more detailed text. Cognitive psychologists working in the field of medical informatics have demonstrated that structured data entry can inadvertently lead to less information, and too much structured data can lead to a loss of cognitive focus, diminishing an individual's ability to see the greater picture (Patel et al l998). In fact the process of composing free text is thought to be integral to accurate information processing (Berg et al 1996). Although this problem might be eased by the combination of free text and structured data entry, as recommended by the AIMS authors in their papers on incident reporting, it is again recommended that

further work must be carried out to establish why when provided with guidance, reporters may be reluctant to give detail. A similar problem has been recorded in relation to radiology reports (Sistrom & Honeyman-Buck 2004), which may be a valuable lesson for incident report design. Tangential to this was the lack of specific data on individual's faulty cognitive processes, as had been so concisely articulated in the interviews and subsequently integrated into the reporter's guidance. A finding which was also at odds with those of the earlier Australian Incident Monitoring studies, where two-thirds of contributory factors identified by reporters were unsafe acts (Runciman et al 1993, Beckman et al, 1996b). This like the other concerns should be systematically explored through a formal evaluation with reporters.

Fear of blame could be the ultimate barrier to reporting both in generic (Vincent et al 1998, Uribe et al 2002, Waring 2005) and drug error reporting schemes (Wakefield et al 1996, 1999b; Hand & Barber 2000, Smetzer et al 2003, Sanghera et al 2007). It also, as has been highlighted – detracts from the central mission in error management – to establish the contributory factors. Perhaps the most encouraging finding was then the change in the nature of the free text which showed no evidence of individual blame. Although major enhancements have of course been made to reporting drug errors in the research trust, the very simple step of allowing reporters to attribute causation and consider systems factors may have laid a very different foundation for action taken, and additionally, facilitated a radical step in the ownership of reporting. However, the propensity to mention practitioners' names remains and may be indicative of a residual inclination to take a person-centred, rather than systems approach, and in this trust should certainly reignite the debate around anonymous reporting. A debate which should centre on achieving a balance between accountability and learning.

Finally, in spite of the guidance emphasising the learning potency of near misses to reporters, there was notable lack of information detailing recovery. Reflecting on

Barach and Small's requirements for a near miss reporting scheme (2002), again highlighted possible future developments for the research trust; to enhance leadership in those units where reporting rates were poor and promote the confidentiality of reporting, the latter adding yet more weight to the option of anonymous reporting.

10.4 Strengths of the study

The literature reviews clearly demonstrated the growing emphasis placed on patient safety across healthcare services. There is a particular concern about drug errors. Their potential for causing patient harm is considerable, as is the financial cost and staff distress if harm actually occurs. Further studies of causation have been recommended as have preventative measures. The reporting of drug errors has received some attention but the knowledge base is limited and development somewhat retarded. This study has sought to address such deficiencies and thus provides an important contribution to patient safety research.

The aim of this thesis demanded a systematic review, a next logical step from the background review, both of these reviews also served as a means of delineating the chosen methods. Specific findings from the review such as the paradoxes of human error [e.g. working less hours may lead to more errors], were also helpful in confirming some of the empirical findings. Without the systematic review, the enhanced scheme would have lacked the broader evidence base required to substantiate but also ultimately appraise the empirical work. It would appear at the time of writing that no other systematic review of drug error reporting exists.

The systematic review also indicated that human error theory as a theoretical framework can facilitate a more ordered and rigorous analysis of error data, a process which also added weight to the existing critique of the overall NCCMERP taxonomy (Zhang 2004; and Kostopoulou 2006). This thesis also suggests that categorising error types and contributory factors from incident report data, based on

a taxonomy without theoretical underpinning, can create considerable difficulties.

Human error theory purports that contributory factors are however, context-bound and as such, they should be studied using methods which are sensitive to the socio-technical as well as socio-cultural elements of error and health professional practice. Human error theory has been used here to analyse the contributory factors but has also played a key role in analysing the data from the reporting process and its associated culture. It has also theoretically underpinned the guidance for the enhanced scheme countering at least one of Hoff et al's claims about the quality of medical error research (Hoff et al 2004). Human error theory may nevertheless fall short as a sole methodology for analysing particular data types, [e.g. the free text in incident report data], especially where the quality of communication is also been assessed. Consequently, Holsti's method for analysing institutional documents was employed, an original approach to analysing report text which can, it is argued also indicate the organisation's maturity in advancing risk management and patient safety. This approach may also have applicability in reporting outside of healthcare.

Snape & Spencer (2003) have argued that epistemological purity is not essential but that different methods can form part of a 'research toolkit' to meet a given real world outcome. Other studies of contributory factors have used more than one method, as documented in the systematic review and the different approaches have either enriched or confirmed the findings. In fact descriptive statistics have been used here to help develop a picture of context, usually seen as the preserve of qualitative methods - through calculating, for example, the frequency of reports citing contributory factors - the process elements of which were then explored through the qualitative interviews. A more substantive goal has however, hand been realised here; several methods have been used but each has complemented and contributed to the development of its successor. Collectively this has led to a multi-faceted but coherent understanding of drug error reporting. Moreover an

evidence base for error reporting schemes has been developed, incorporating a taxonomy of contributory factors that advances a systems approach and crucially, the opportunity for practitioners to actively learn at the point of reporting. In fact, the contributory factors approach is now been adopted by other departments in the research trust as means of analysing the causation of falls in elderly care, and in the misuse and failure of medical devices in the medical physics department.

The Stage 1 and 2 findings demonstrated that drug errors, and their reporting, are multi-disciplinary problems. The interview data – based as it was on a quota-based multi-disciplinary sample – exposed various dimensions of error causality and reporting. Unlike many studies included in the systematic review however, the multi-disciplinary data was then used to plan and implement an enhanced reporting scheme which, based on the participants' views served to advance the premise of learning rather than blame, and in essence, a multi-disciplinary solution.

This study was by the nature of the enhanced reporting scheme that it helped develop, the progeny of a responsive environment - an acute NHS trust with its inherent policies, procedures, subcultures and cadres. While this might be seen as a weakness, it is seen here as a strength. As the findings and eventually the pilot scheme passed through numerous committees, forums, and eventually the piloting departments, it became apparent to the author that *research process* had facilitated a broader understanding of medical error among those involved.

The Cooksey Review (House of Commons Science & Technology Committee 2007) has stressed the importance of translating research findings into practice to increase the effectiveness of health care provision. The reporting scheme here has been retained by the piloting departments after the pilot period and has been voluntarily adopted by several other units in the trust. While this may be suggestive of a reasonable face validity it may, more importantly, indicate that this scheme has a greater practical utility than its predecessor. Positive assumptions about utility

may also be borne out by the strong interest shown by several external organisations who have joined a multi-centred evaluation of the enhanced scheme. Additionally, the research trust is currently integrating the enhanced report format into a proposed bid for a trust-wide electronic reporting process.

10.5 Limitations of the study

This study was carried out in one health care organization, which is also a teaching hospital, and as such the quantitative findings are unlikely to be generalizable. However, although the Trust has received explicit recognition for its clinical governance processes, it is claimed that the organization remains likely to be theoretically representative of many acute hospital trusts across the United Kingdom and in other similar health economies. The corroboration between the findings here and in other studies concerning both the contributory factors and the process and culture of drug error reporting supports this position.

It is sometimes evident that a methodological strength might also illuminate an associated weakness. The application of human error theory, has added structure and purpose to the data analysis and ultimately informed the design of the enhanced scheme. As the empirical base of medical error reporting has been largely atheoretical (Karsh et al 2006), this is a strength of the study. However, unlike other studies of contributory factors in drug errors (Dean et al 2002b, Taxis & Barber 2003, Beso et al 2005, Sanghera et al 2007) and elsewhere (Kostopoulou, 2006), where the analysis has ultimately discriminated between the different levels at which contributory factors reside in an organisation [i.e. unsafe acts, workplace factors, and latent conditions], the factors described in this study were ordered differently. This was also evident in the enhanced report format. Reporters were asked to identify any unsafe acts in their description of the circumstances, and then consider these *alongside* a choice of error producing and organisational factors. Reporters were then asked to consider the interplay of these factors and grade

their importance. Although the approach in this study might be viewed as slurring one of the fundamental elements of human error theory, it is defended on three points. First, it was felt that the nature of unsafe acts, rarely described in these data but proximal to the reporter, could be more successfully drawn out of the reporter through *the guided* free text. Secondly, it goes some way to accommodating the criticism that the organisational accident model is inappropriately unilateral (Dekker 2006); but also if factors are often jointly sufficient, their interplay should be recorded. Furthermore, reporting schemes should be tailored to improve their utility in the organisational setting (Walshe 2007), and because of this, it was thought that the original terminology of the accident model could be obfuscating to reporters. Other weaknesses are now addressed by stage of the study.

Another limitation lay in the process and structure of incident reporting: reports are voluntarily submitted, biased by psychological phenomena (described in Chapter 2), not necessarily representative of the organization other than those who report, and are limited by their degree of detail, objectivity and clarity (Helmreich & Merrit, 1998).

Additionally, the final year of the incident report data are now 5 years old, even so it does, as previously stated, provide a longitudinal assessment of how a healthcare organization and its members have addressed this element of reporting over a period of time when there was an increasing emphasis on reducing risk (Armitage et al 2007). The intensive and time consuming process of reviewing 1253 reports might have been appropriately reduced by applying the concept of saturation, but this was rejected, largely as a result of the author's (perhaps unnecessary) need to develop a sustained analysis.

One of the predominant methodological issues identified in Chapter 3 was the choice of denominator for reported errors per specialty. As was seen, the most

common denominators to calculate an error rate are – depending on the method of data collection - errors per dose, errors per prescription item, and errors per opportunity for error. Whatever denominator is chosen here, the resultant rate is arguably of less meaning than the error rate in an observational study as the reporting rate in a study of error reporting can only be a measure of errors voluntarily reported. Therefore, the most suitable denominator is *all errors made*. The resources available for this study precluded the multi-method study required to calculate a cross-departmental (actual) error rate. The second choice would then have been errors per admission. Unfortunately this would, due to the several wards changing by specialty but not ward number over the 5 year study period, have given an inaccurate denominator. The third choice was finished consultant episodes or FCEs, which was not ideal but a response to reality. The previous issue is also a stark reminder that incident report data cannot be a robust method of error detection.

A further limitation was the lack of mutual exclusiveness in the categories chosen for the contributory factors, and because of this not strictly adhering to Holsti's original guidance. However, difficulty with mutual exclusiveness is not novel in categorising errors – particularly causation (Beckmann et al 1996a, Avery 2003), something that is also emphasised to users of the NCCMERP taxonomy (NCCMERP 1998, Section 80). It may be easier if you are the protagonist, and have literally lived the experience, but in a textual analysis of report data, especially if the reporter is vicarious, categorization is challenging. A checking error may be integral to a knowledge deficit or knowledge misapplied, both of which could be exacerbated by ineffective supervision. The order of events and their conceptual separation is not easily deciphered. Cause and effect may be interchangeable. 'Performance deficit' as a contributory factor in the NCCMERP taxonomy is defined as 'where a practitioner should have known better but did not act accordingly' (Storch 2005), the problem is that all the factors in the example above could include

a performance deficit. The Kappa scores highlighted the ambiguity in this term, despite it being a published category. However, the Kappa scores should be treated with some caution due to the inherent cognitive biases and confidence levels of reviewers (discussed in relation to other studies in Chapter 2, Section 2.9.3), and the commonality of events being reviewed (discussed on page 126).

The rich data which emanated from the data in Stage two of the study gave considerable power to the participants' standpoint, as would be expected in qualitative research (Strauss 1987). However, the threat of response bias is ever present. The interview is always a social encounter (Murphy et al 1998), and in this study an encounter based on an especially sensitive topic. Mindful of the critique of interviews in error research highlighted in the systematic review, the participants may well have inclined to produce data which would *not* create a negative self-image, which as previously discussed, may have accounted for the considerable emphasis on workload and the chaos of practice.

The design of the new reporting scheme which formed stage three of the study inevitably had limitations. The sample was purposive rather than random, which despite the rationale given, does carry a threat of selection bias. Furthermore, reporters are likely to have used an arbitrary set of values to rate the importance of their contributory factors – perhaps swayed by an avoidance of the negative self-image referred to above. Halo effect was then a threat to validity as practitioners may have chosen factors influenced by their previous experiences of reporting or alternatively, their perception of the consequences. As has been pointed out, due caution should be exercised when interpreting thus type of data, however it is argued that capturing more structured descriptions of both circumstances and causation in spite of such bias can be valuable. Such descriptions at least provide a more tangible perspective, which can be accepted or challenged by a senior party, and also compared to other sources of safety data.

Importantly, the small sample of reports received in the mini-pilot did not allow for a robust analysis or the drawing of firm conclusions. Additionally, the intensive training process may have had a significant influence on the quantity and quality of reporting, perhaps becoming something of an extraneous variable. This forged a strong case for the multi-centred pilot previously discussed and now in progress. Finally, the absence of a discrete patient factor in the reporting scheme [e.g. patient confusion] may have been a weakness, although Bates et al (1999) have commented on patient factors being less influential than systems factors.

10.6 Conclusion

This thesis has, through an extensive review of the human error literature, and the specific systematic reviews of the contributory factors in drug error and their reporting developed an evidence base for an important component of incident reporting. The ensuing empirical data has added to the evidence base and led to the development and active use of a novel reporting scheme which is especially timely when incident reporting continues to be strongly advocated as a means of combating error through learning.

Reason has suggested that voluntary incident reporting is the lifeblood of an 'informed culture' (Reason 1990), although such reporting in the health service may not yet be the perfect tool for either reporters or their superiors. However, it can illuminate the dominant safety culture in a given unit or even the broader organisation. It might also, if structured for learning, create safety information while simultaneously re-enfranchising reporters. It must though, be compared and contrasted with other forms of safety data, all of which have strengths but also weaknesses. The data here should, through recourse to the philosophy of human error theory, encourage acceptance of what are often seen as unpalatable notions [e.g. those units who report more errors are often the ones with the stronger safety culture]. The hierarchy of contributory factors elucidated in this thesis and their

apparent interaction should also alert organisations to the particular demands of practice but also the nature of practice. Although factors such as interruptions may be challenging in their potential consequences for the finite resources of service providers, and critical alerts; they may also indicate the need for reform.

Given the fact that several previous studies have found practitioners' perceptions of medicines management as being low value, and that a similarly low value can also be attributed to drug error reporting, urgent action is demanded. Reporting should be part of an integrated approach to medicines management. This must be a multi-disciplinary approach where learning is the key driver as a means of creating an error wise culture. Ultimately, following an error, the act of reporting becomes second nature. The study concludes with several specific recommendations as a reflection of the conclusion.

10.7 Recommendations

It is well documented that error stems from the interaction between individuals and systems, having psycho-social, cognitive and technical components. The contributory factors in drug errors are not atypical. Although this may not be apparent from report data, it is probably a known given for most practitioners. Problematic communication is a persistent factor. It is, however, also clear from this study that while resources may have to be improved to combat some errors, reform of practice and some practitioners' attitudes may also require attention. Error wisdom has many constituents.

The knowledge of contributory factors developed here, and elsewhere, can provide a conceptual foundation for future reporting schemes. A knowledge of human error theory can further improve the structure and process of reporting by informing reporter guidance and helping them elucidate the circumstances around an error. Reporters should also be assured that error does not always lead to failure, and safety is not about defending systems from erring humans. The act of reporting

may then have the potential for learning.

To achieve such learning, organisations must also adopt an even-handed, structured approach to error reporting, and reflect on the need for specific training around error and causation, mindful of the authors' experiences here. Reporting should be characterised by a clear emphasis on error prevention, as well as rapid and constructive reporter feedback, at a local, and if appropriate and feasible, organisational level. Aware that some departmental cultures may have made more rapid advances than others in error management, organisations might capitalise on these departments to demonstrate to some of their less enthusiastic peers that reporting need not be a thankless treadmill. A completed report is also far more than the documentation of an error, it can also be an insight into the maturity of an organisation or department's safety culture. If this is accepted by all those who play a part in reporting, it might also be a convenient and cost effective way of evaluating, and thus improving the process.

An open debate should be activated concerning the separation of drug error reporting from mainstream or generic reporting schemes. Electronic reporting may be helpful in diffusing any subsequent anxiety about creating an unmanageable paper mountain as reporters could choose an error report type through a drop down menu.

Further research should be carried out to examine more closely the effectiveness of attributing causation through reporting, and why some practitioners, whether divided by profession or other socio-cultural groupings, do not want to report. The societal as well as organisational implications of studies such as this suggest it may also be pertinent to examine the role of patients in reporting safety incidents such as drug errors, as perceived by professionals, but also patients. Whatever the methods employed in future studies, there should be a distinct clarity in operational definitions and an explicit acknowledgement of the other common methodological

issues highlighted here: the need for accurate denominators (if an epidemiological approach is taken), the sensitivity of methods to the errors being studied, and the establishing of reliability measures. Furthermore, although taxonomies are essential in establishing validity and accuracy of understanding, their reliability should be judged on the basis of their application to practice as well as their theoretical underpinning.

Drug errors are multi-disciplinary problems, any solutions must be multi-disciplinary. Consequently, the analysis of contributory factors and the development of drug error reporting schemes should be a multi-disciplinary pursuit.

REFERENCES

Aasland OG Forde R. (2005) Impact of feeling responsible for adverse events on doctors' personal and professional lives: the importance of being open to criticism from colleagues. Quality and Safety in Health Care **14** 13-17

Adams D. (2001) Number of deaths caused by medical errors under dispute. AMednews.com Accessed 22.4.04

Adams J. (1995) Risk. London, UCL Press.

Agency for Healthcare Research & Quality (2003) AHRQ's Patient Safety Initiative: Building Foundation, Reducing Risk. Rockville, Maryland: AHRQ.

Ajzen I. (1991) The theory of planned behaviour. Organisational Behaviour and Human Decision Processes **50**: 179-211.

Alderhey Hospital (2006) Personal Communication 22.3.06 with Risk Management Department. Liverpool.

Allen EL, & Barker KN. (1990) Fundamentals of medication error research. American Journal of Hospital Pharmacy **47**: 555-571.

Allen LaPointe NM, Jollis JG. (2003) Medication errors in hospitalised cardiovascular patients. Archives of Internal Medicine **163**: 1461-1466.

Allnutt MF (1987) Human factors in accidents. British Journal of Anaethesia **59**: 856 864.

Amalberti R, Auroy Y, Berwick D, Barach P. (2005) Five System Barriers to Achieving Ultrasafe Health Care. Annals of Internal Medicine **142**(9): 756-764.

Amalberti R, Vincent C, Auroy G. (2006) Violations and migrations in health care: a framework for understanding and management. Quality & Safety in Health Care **15** (Supplement 1): i66-i71.

Anderson DJ, Webster CS. (2001) A systems approach to the reduction of medication error on the hospital ward. Journal of Advanced Nursing **35**: 34-41.

Andrews LB, Stocking C, Krizek T, Gottlieb L, Krizek C, Vargish T, Siegler M. (1997) An alternative strategy for studying adverse events in medical care. The Lancet **349**(9048): 309-313.

Armitage G. (2005) Drug errors, qualitative research and some reflections on ethics Journal of Clinical Nursing **14**: 869-875.

Armitage G, Chapman EJ. (2007) Incident reporting: a curate's egg? Journal of Integrated Care Pathways **9** 1-6.

Armitage G, Hodgson I. (2004) Using ethnography (or qualitative methods to investigate medication errors: a critique of a published study. Journal of Research in Nursing (*Formally NTResearch*) **9** (5): 2-9.

Armitage G, Knapman H. (2003) Adverse events in drug administration: a literature review. Journal of Nursing Management **11**: 130-140.

Armitage G, Newell RJ, Wright J. (2007) Drug errors and their reporting in a British

acute hospital trust. Clinical Governance **12** (2): 102-114.

Armstrong D, Gosling A, Weinman J, Marteau T. (1997) The place of inter-rater reliability in qualitative research: an empirical study. Sociology **31**: 597-606.

Arthur S, Nazroo J (2003) Designing Fieldwork Strategies and Materials. In Ritchie J, Lewis J. Qualitative Research Practice. p.109-137. London: Sage.

Ash JS, Gorman PN, Seshadri V, Hersh WR, (2004) Computerised Physician Order Entry in US Hospitals: Results of a 2002 Survey. Journal of the American Medical Informatics Association **11**: 95-99.

Ashcroft D, Cook J and (2006) Retrospective analysis of medication incidents reported using an on-line reporting system. Pharmacy World & Science **28**(6): 359-65.

Atkinson P, Coffey A (1997) Analysing documentary realities. In Silverman D. Qualitative Research: Theory, method and Practice. London: Sage.

Avery T. (2003) Classifying and identifying errors. Quality & Safety in Health Care **12**: 404.

Ayeko M. (2002) Integrated Safety Investigation Methodology (ISIM): Investigation for Risk Mitigation. Proceedings of the First Workshop on the Investigation and Reporting of Incidents & Accidents, 18.7.02. Department of Computing, University of Glasgow: University of Glasgow.

Bagian JP, Lee C Gosbee J DeRosier J Stalhandske E Eldridge N Williams R Burkhardt M. (2001) Developing and deploying a patient safety program in a large health care delivery system. Joint Commission in Accreditation of Healthcare Organisations **27**(10): 522-532.

Baker H (1997) Rules Outside The Rules for Administration of Medication: A Study in New South Wales, Australia. Journal of Nursing Scholarship **29** (2): 155-158.

Baker GR, Norton PG (2002) Patient Safety and Healthcare Error in the Canadian Healthcare System. A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere: A Report to Health Canada. Ontario: Canada

Baker GR. (2004) Commentary: Harvard Medical Practice Study. Quality & Safety in Health Care **13**: 151-152.

Baker GR, Norton PG Flintoft V, Blais R, Brown A, Cox J, Etchells E, Ghali WA, Hebert P, Sumit RM. (2004) The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. Canadian Medical Association Journal **170**: 1678-86.

Bale J. (2006) Allergic to penicillin: written in her notes and on her armband but a doctor gave her the drug anyway and she died. In The Times March 21st 2006, p3.

Barach P, Small SD, Kaplan H. (1999) Designing a confidential safety reporting system: in depth review of thirty major medical incident reporting systems, and near miss systems in the nuclear, aviation, and petro-chemical industries. Anaestheology **91**: A1209.

Barach P, Small SD (2000) Reporting and preventing medical mishaps: lessons

from non-medical near miss reporting systems. British Medical Journal **320**: 759-763.

Barber N, Rawlins M, Dean Franklin B. (2003) Reducing prescribing error: competence, control and culture. Quality & Safety in Health Care **12**(Supplement 1): i29-i32.

Barbour R. (2001) Checklists for improving rigour in qualitative research: a case of the tail wagging the dog. British Medical Journal **322**: 1115-7.

Barker KN, Flynn, EA, Pepper, GA, Bates, DW, Mikeal, RL. (2002) Medication errors observed in 36 health care facilities. Archives of Internal Medicine **162**: 1897-1903.

Baron J, Hershey JC. (1988) Outcome bias in decision evaluation. Journal of Personality and Social Psychology **54**: 569-579.

Bates DW. (1999) Frequency, consequences and prevention of adverse drug events. Journal of Quality in Clinical Practice **19**: 13-17.

Bates DW, Leape LL, Petrycki S. (1993) Incidence and preventability of adverse drug events in hospitalised adults. Journal of General Internal Medicine **8**: 289-294.

Bates DW, Cullen, DJ, Laird, N, Petersen, LA, Small, SD, Servi, D, Laffel, G, Sweitzer, BJ, Shea, BF, Hallisey, R, Vander Vliet, M, Nemeskal, R, Leape, L (1995a) Incidence of Adverse Drug Events and Potential Adverse Drug Events. Journal of the American Medical Association **274**(1): 29-34.

Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. (1995b) Relationship between medication errors and adverse drug events. Journal of General Internal Medicine **10**: 199-205.

Bates, DW; Leape, LL; Cullen, DJ; Laird, N; Petersen, LA; Teich, JM; Burdick, E; Hickey, M; Kleefield, S; Shea, B; Vander Vliet, M; Seger, DL. (1998) Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. Journal of the American Medical Association. 280:1311–6.

Bates DW, Miller EB, Cullen DJ, Burdick L, Williams L, Laird N, Petersen LA, Small SD, Sweitzer BJ, Vander Vleit M, Leape LL. (1999) Patient Risk Factors for Adverse Drug Events in Hospitalised Patients. Archives of Internal Medicine **159**: 2533-2560.

Battles JB, Kaplan HS, Van der Schaff T, Shea CE (1998). The Attributes of Medical Event Reporting Systems. Archives of Pathological Laboratory Medicine **122**: 231-238.

BBC News Online. (2004) Doctors not reporting errors. Accessed 2.12.04. http://news.bbc.co.uk/1/hi/health/3840257.stm.

Beatty P. (2006) Technology, informatics and patient safety. In Walshe K. & Boaden R. Patient Safety: research into practice. p66-78. Maidenhead, Open University Press.

Beckman U, Baldwin I, Durie M, Morrison A, Shaw L (1998) Problems associated with nursing staff shortage: an analysis of the first 3600 incident reports submitted to the Australian Incident Monitoring study. Anaesthesia & Intensive Care **26**(4): 396-400.

Beckman U, West LF Groombridge GJ Baldwin I Hart GK Clayton DG Webb RK Runciman WB. (1996a) The Australian Monitoring Study in Intensive Care: AIMS-ICU. The development and evaluation of an incident reporting system in intensive care. Anaesthesia & Intensive Care **24**(3): 314-319.

Beckman U, Baldwin I Hart GK Runciman WB. (1996b) The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. An analysis of the first year of reporting. Anaesthesia & Intensive Care **24** (3): 320-329.

Beckman U, Runciman WB. (1996) The role of incident reporting in continuous quality improvement. Anaesthesia and Intensive Care **24**: 311-313.

Berg M. (1996) Practices of reading and writing. Sociology of Health & Illness **18**: 499-524.

Berman J, Collier D. (1996) The collection and use of near miss data: is no blame just wishful thinking? Managing Risk in an Ever Changing Organisational Climate. Safety and Reliability Society Conference 9.10.06. Swindon, England.

Berwick D, Nolan T. (1998) Physicians as leaders in improving health care. Annals of Internal Medicine **128** (4): 289-292.

Beso A, Dean Franklin B, Barber N. (2005) The frequency and potential causes of dispensing errors in a hospital pharmacy. Pharmacy World & Science **27**: 182-190.

Billings CE. (1998a) Incident Reporting Systems in Medicine and Experience with the Aviation Reporting System. A tale of two stories: contrasting views of patient safety. W. D. Cook RI, Miller CA. North Adams, MA., National Patient safety Foundation**:** 52-61.

Billings CE. (1998b) The NASA Aviation Safety Reporting System. Enhancing Patient Safety and Reducing Errors in Healthcare, Chicago, National Patient Safety Foundation Conference.

Bilsing-Palacio L, Schell KL. (2003) Signal probability. Psychological Reports **93**: 343-352.

Blendon RJ, DesRoches CM, Brodie M, Benson JM, Rosen AB, Schneider E, Altman DE, Zapert K, Herrmann MA, Steffenson AE. (2002) Views of practicing physicians and the public on medical errors. New England Journal of Medicine **347**: 1933-1940.

Boaden R, Walshe K. (2006) Conclusion - and the way forward. In Walshe K & Boaden R. Patient Safety: research into practice. Maidenhead, Open University Press**:** 217-231.

Bombi JA, Ramirez J, Sole M, Grau JM, Chabas E et al. (2003) Clinical and autopsy correlation evaluated in a university hospital in Spain (1991-2000) Pathology: Research and Practice **199** 1 9-14

Bond CA, Raehl CL. (2001) Pharmacists' assessment of dispensing errors: risk factors, practice sites, professional functions and satisfaction. Pharmacotherapy **21** (5): 614-626.

Bosk CL. (1979) Forgive and Remember: managing medical error. Chicago: University of Chicago Press.

Bowers D. (2002) Medical Statistics from Scratch. London: Wiley Press.

Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG. (1991) Incidence of adverse events and negligence in hospitalised patients. New England Journal of Medicine **324**(6): 370-376.

Brown C, Patil P, Hofer T, Johal A, Thomson R, Lilford RJ, Nicholl J, Dean Franklin B. (2006) An epistemology of patient safety research: a framework of study design and interpretation. Report prepared for the MRC UK.: University of Birmingham.

Bruce J, Wong IK (2001) Parenteral drug administration errors by nurses on acute admissions wards during day duty. Drug Safety **24**: 855-62.

Buckley TA, Short TG, Rowbottom YM, Oh TE. (1997) Critical Incident Monitoring in the Intensive Care Unit. Anaesthesia **52**(403-9).

Busse DK, Wright DJ. (2000) Classification and Analysis of Incidents in Complex Medical Environments. Topics in Health Information Management **20** (4): 1-11.

Butler J. (2002) Learning from the Aviation Industry. Patient Safety in the NHS: The Contribution of Education and Training. October 24th 2002. Royal College of Obstetricians and Gynaecologists.

California Medical Association (1977) California Medical Hospital Association Report on Medical Insurance Feasibility San Francisco, California Medical Association.

Cantrill J (2006) Medication Error 2. Patient Safety Research Portfolio: Development of Capacity and Evaluation of IT Solutions. Birmingham, Dept, Public Health & Epidemiology: Birmingham University.

Caplan RA, Posner KL, Cheney FW. (1991) Effect of outcome of physician judgements of appropriateness of care. Journal of the American Medical Association **265**: 1957-60.

Carlton G, Blegen MA. (2006) Medication-related errors: a literature review of incidence and antecedents. Annual Review of Nursing Research **24**: 19-38.

Carroll JS, Quijada MA. (2004) Redirecting traditional professional values to support safety: changing organisational culture in health care. Quality & Safety in Health Care **13** (Supplement ll): ii16-ii21.

Carthey J, de Leval MR, Reason J. (2001) Institutional resilience in healthcare systems. Quality & Safety in Health Care **10**: 29-32.

Catlin A. (2004) A source of tremendous loss. Pediatric medical errors part 2: case commentary. Pediatric Nursing **30**(4): 331-333.

Cavell GF, Hughes DK (1997). Does computerised prescribing improve the accuracy of drug administration? Pharmaceutical Journal **259**(782-784).

Clarke S. (1998) Organisational factors affecting the incident reporting of train drivers. Work and Stress **12**(1): 6-16.

Classen DC, Metzger J. (2003) Improving medication safety: the measurement conundrum and where to start. International Journal for Quality in Health Care **15** (1

(Supplement)): i41-i47.

Classen DC, Pestotnik SL Scott Evans R Burke JP (1991) Computerised surveillance of adverse drug events in hospital patients. Journal of the American Medical Association **266**: 2847-51.

Clift M. (2007) Audit of medication administration errors by time of day in a paediatric unit. Personal Communication with Michael Clift at the Whittington Hospital NHS Trust, London.
Clinton H, Obama B. (2006) Making patient safety the centerpiece of medical liability reform. New England Journal of Medicine **354**(21): 2205-2208.

Cohen J. (1960) A coefficient of agreement for nominal scales. Educational and Psychological Measurement **20**(37-46).

Cohen MR. (2000) Why error reporting systems should be voluntary. British Medical Journal **320**: 728-9.

Cook DJ, Mulrow CD, Haynes RB. (1997) Systematic reviews: synthesis of best evidence for clinical decisions. Annals of Internal Medicine **126**(5): 376-380.

Cooper JB, Newbower RS, Long CD. (1978) Preventable Anaesthesia Mishaps: a study of human factors. Anaesthesiology **49**: 399-406.

Corrigan JM (2001) Statement: Concerning Patient Safety and Medication Errors. To the Senate Special Committee in Ageing. 3.5.2001. Washington.

Cousins D, Sabatier B, Begue D, Schmitt C, Hoppe-Tichy T. (2005) Medication errors in intravenous drug preparation and administration: a multi-centre audit in the UK, Germany and France. Quality & Safety in Health Care **14**: 190-195.

Crawford SY, Cohen MR, Tafesse E. (2003) System factors in the Reporting of Serious Medication Errors in Hospitals. Journal of Medical Systems **27**(6): 543-551.

Cullen DJ, Bates DW Small SD Cooper JB Nemeskal AR Leape L. (1995) The incident reporting system does not detect adverse drug events: a problem for quality improvement. Journal of Quality Improvement **21**(10): 541-8.

Dalby K. (2001) How to avoid common prescribing errors. Prescriber (5th June): 83-86.

Daniels C, Marlow, P. (2005) Literature Review on the Reporting of Workplace Injury Trends. Buxton, Health & Safety Laboratory.

Davis P, Lay-Yee R, Schug S, Briant R, Scott A, Johnson S, Bingley W. (2002) Adverse events in New Zealand. New Zealand Medical Journal **114**(1131): 203-5.

Dean B (2003) Adverse drug events: what's the truth? Quality and Safety in Health Care **12**: 165-6.

Dean B, Barber N (2001) Validity and reliability of observational methods for studying medication administration errors. American Journal of Health System Pharmacy **58** (1): 54-59.

Dean B, Schachter M, Vincent C, Barber N. (2002a) Prescribing errors in hospital inpatients: their incidence and clinical significance. Quality & Safety in Health Care

11(340-344).

Dean B, Schacter M Vincent C Barber N (2002b) Causes of prescribing errors in hospital inpatients: a prospective study. The Lancet **359**: 1373-1378.

Dejong D, Brookins LH, Odgers L (1998) Multi-disciplinary design of a medication error reporting system. Hospital Pharmacy **33**(11): 1372-7.

Dekker S (2006) Field Guide to Human Error. Aldershot, Ashgate Publishing.

Denzin NK, & Lincoln YS (2000) Handbook of Qualitative Research. Thousand Oaks, Sage.

Department of Health (1999) Clinical Governance: Quality in the NHS. London, The Stationary Office.

Department of Health (2000a) An Organisation With A Memory. Report of an expert group on learning from adverse events in the NHS, The Stationery Office.

Department of Health (2000b) The NHS Plan, HMSO.

Department of Health (2001) Doing Less Harm. London, The Stationary Office.

Department of Health (2001a) The Bristol Royal Infirmary Inquiry. Learning from Bristol: the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. S. I. Kennedy, The Stationary Office.

Department of Health (2004) Building a Safer NHS for Patients: Improving medication safety. London, HMSO.

Desikan R, Krauss MJ, Claiborne D, Rachmiel EC, Bailey T, Fraser VJ (2004) Reporting of adverse drug events: examination of a hospital incident reporting system. Advances in Patient Safety **Volume**, DOI:

Dineen M, Walshe K (1999) Incident reporting in the NHS. Risk Management Health Care Risk Report: p17-19.

Dobrzanski S, Hammond I, Khan G, Holdsworth H. (2002) The nature of hospital prescribing errors. British Journal of Clinical Governance **7**(3): 187-193.

Donaldson L. (2006) How can we learn more quickly from error? www.saferhealthcare.org.uk/IHI/Topics/ManagingChange/Features/learnquickly. Accessed 3.9.07.

Donchin Y, Gopher D, Olin M, Badihi Y, Biesky M, Sprung CL. (1995) A look into the nature and causes of human error in the intensive care unit. Critical Care Medicine **23**(294-300).

Ebbeson M. (2001) Drug related deaths in a department of internal medicine. Archives of Internal Medicine **161**: 2317-2323.

Edmondson AC (1996) Learning from mistakes is easier said than done: group and organisational influences on the detection and correction of human error. Journal of Applied Behavioural Science **32**(1): 5-28.

Edmondson AC (2004) Learning from failures in health care: frequent opportunities, pervasive barriers. Quality & Safety in Health Care **13**: ii3-ii9

Evans SM, Berry JG Smith BJ Esterman A Selim P O'Shaugnessy J DeWit M. (2006) Attitudes and barriers to incident reporting: a collaborative study. Quality and Safety in Health Care **15**: 39-43.

Evans SM, Smith BJ, Esterman A, Runciman WB, Maddern G, Stead K, Selim P, O'Shaugnessy J, Muecke S, Jones S. (2007) Evaluation of an intervention aimed at improving voluntary incident reporting in hospitals. Quality and Safety in Health Care **16**: 169-175.

Finch H. & Lewis J. (2003) Focus Groups. In Ritchie J, Lewis J. Qualitative Research Practice. p.170-198 . London, Sage.

Fischoff B. (1975) The effect of outcome knowledge on judgement under uncertainty. Journal of Experimental Psychology: human perception and performance **1**(3): 288-299.

Flanagan JC. (1954) The Critical Incident Technique. Psychological Bulletin **51**: 327-58.

Flynn EA, Barker KN Pepper GA Bates DW Mikeal RL. (2002) Comparisons of methods for detecting medication errors in 36 hospitals and skilled nursing facilities. American Journal of Health System Pharmacy **59**: 436-46.

Fogarty GJ, McKeon CM. (2006) Patient safety during medication administration: the influence of organisational and individual variables on unsafe work practices and medication errors. Ergonomics **49**(5-6): 444-456.

Folli HL, Poole RL, Benitz et al. (1987) Medication error prevention by clinical pharmacists in two children's hospitals. Pediatrics **79**(718-722).

Fontana A, Frey JH. (2000) The interview: from structured questions to negotiated text. In Lincoln Y. Denzin NK. Handbook of Qualitative Research. P. 645-672. Thousand Oaks, California, Sage**.**

Franklin BD, Vincent C, Scachter M, Barber N (2005) The incidence of prescribing errors in hospital inpatients: an overview of the research methods. Drug Safety **28**(10): 891-900.

Furukawa H, Bunko H, Tsuchiya F, Myamoto K. (2003) Voluntary Medication error reporting programme in a Japanese National University Hospital. Annals of Pharmacotherapy **37**: 1716-1732.

Ghaleb MA, Barber N, Dean Franklin B, Wong ICK. (2005) What constitutes a prescribing error? Quality and Safety in Health Care **14**: 352-357.

Ghaleb MA, Wong ICK (2006) Medication errors in paediatric patients. Archives of Disease in Childhood **91**: 20.

Giacomini MK, Cook DJ. (2000) User's Guide to the Medical Literature. Journal of the American Medical Association **284**(3): 357-362.

Gidley B. (2004) Doing Historical and Archival Research. In Seale C. Researching Society and Culture. p249-264.London, Sage**.**

Gilbert GN, Mulkay M. (1984) Opening Pandora's Box: a sociological analysis. Cambridge, Cambridge University Press.

Giles S, Cook G, Jones M, Todd B, Mason M, Walshe K. (2004) Developing a multi-professional agreed list of adverse events for clinical incident reporting in trauma and orthopaedics. Clinical Governance **9**(4): 225-231.

Giles S, Fletcher, M, Baker, M, Thomson, R (2006) Incident reporting and analysis. In Walshe K. & Boaden R. Patient Safety: research into practice. P108-117. Maidenhead, Open University Press.

Gladstone J. (1995) Drug Administration Errors: a study into the factors underlying the reporting of drug errors in a district general hospital. Journal of Advanced Nursing **22**(4): 628-637.

Gordon PC, Llewellyn RL, James MFM (2006) Drug administration errors by South African anaesthetists. South African Medical Journal **96** (7) 630-632.

Greenwood M, Woods HM. (1919) A report on the incidence of industrial accidents with special reference to multiple accidents. London, Industrial Fatigue Research Report No.4.

Grol R, Baker R, Moss F. (2004) Quality Improvement Research: Understanding the Science of Change in Health Care. London, BMJ Books.

Grunberg L, Moore S, Greenburg E. (1996) The relationship of employee ownership and participation to workplace safety. Economic and Industrial Democracy **17**: 221-241.

Guba EG, Lincoln YS. (1989) Fourth generation evaluation. Newbury Park, Sage.

Gubrium J, Holstein J. (2002) Handbook of Interview Research: context and method. Thousand Oaks, Sage.

Haley RW, Culver DH, White JW, Morgan WM, Munn VP, Hooton TM. (1985) The efficacy of infection surveillance and control programmes in preventing nosocomial infection in US hospitals. American Journal of Epidemiology **121**(2): 182-205.

Hand K, Barber N. (2000) Nurses' attitudes and beliefs about medication errors in a UK hospital. The International Journal of Pharmacy Practice **8**: 128-34.

Hartley GM, Dhillon S. (1998) An observational study of the prescribing and administration of intravenous drugs in a general hospital. International Journal of Pharmacy Practice **6**: 38-45.

Haw C, Stubbs J, Dickens G. (2007) An observational study of medication administration errors in old-age psychiatric inpatients. International Journal for Quality in Health Care **19**(4): 210-216.

Hayward RA, Hofer TP. (2001) Estimating hospital deaths due to medical error. Journal of the American Medical Association **286**(4): 415-420.

Health & Safety at Work Act. (1974) HMSO London.

Health & Safety Executive (1999) Reducing error and influencing behaviour. Suffolk, HSE Books.

Heinrich HW. (1980) Industrial Accident Prevention: a scientific approach. New York, McGraw Hill.

Helmreich R, Merrit A. (1998) Culture at work in aviation and medicine. Aldershot, Ashgate.

Helmreich RL, Foushee HC. (1993) Why crew resource management? The empirical and theoretical bases of human factors training in aviation. In Weiner EL, Kanki BJ. Helmreich RL Cockpit Resource Management. p3-45..San Diego, Academic Press**.**

Higton P. (2006) Improving patient safety: a human factors approach at University Hospitals Coventry. www.saferhealthcare.org.uk Accessed 20.9.07

Hintong T, Waraporn C, Thienthing S, Nakcharoenwaree S. (2005) An analysis of the drug error problem in the Thai anaesthesia incidents study. Journal of the Medical Association of Thailand **88** (Supplement 7): S118-S127.

Ho CYW, Dean BS, Barber ND. (1997) When do medication errors happen to hospital inpatients? International Journal of Pharmacy Practice **5**(91-96).

Ho CYW, Dean BS, Barber ND (2001) When do medication administration errors happen to hospital in-patients? International Journal of Pharmacy Practice **5**: 91-96.

Hoff T, Jameson L, Hannan E, Flink E. (2004) A Review of the Literature Examining Linkages between Organisational Factors, Medical Errors, and Patient Safety. Medical Care Research and Review **61**(1): 3-37.

Hogan H, Olsen S, Scobie S, Chapman J, Sachs R, McKee M, et al. (2007) What can we learn about patient safety from information sources within an acute hospital - a step on the ladder of integrated risk management? Accepted Quality and Safety in Health Care – to be published 2008.

Hollnagel E. (1983) Human Error. NATO Conference on Human Error, Bellagio, Italy.

Hollnagel E. (1993) Human Reliability Analysis: Context and Control. London, Academic Press.

Hollnagel E, Amalberti R. (2001) The emperor's new clothes: or whatever happened to 'human error'? Proceedings of the 4th International Workshop on Human Error, Safety, and Systems Development. June 11th 2001, Linkoping University, Sweden.

Hollnagel E, Woods D, Leverson NG. (2006) Resilience, Engineering Concepts and Precepts. Aldershot, Ashgate Press.

Holstein JA, Gubrium JA (2004) Context: working it up, down and across. In Seale C, Gobo G, Gubrium JF, Silverman D. Qualitative Research Practice. p297-311.London, Sage**.**

Holsti OR. (1969) Content Analysis for the Social Sciences & Humanities. Reading, Massachusetts, Addison Welsley.

House of Commons Science and Technology Committee (2007) The Cooksey Review: Government Response to the Committee's Third Report of Session 2006-7. Third Report.

Howe A (2006) Patient Safety: education, training and development. In Walshe K.

Boaden R. Patient Safety: research into practice. P187-197. Maidenhead, Open University Press.

Huberman AM, Miles MB. (2002) The Qualitative Researcher's Companion. Thousand Oaks, Sage.

Hudson P, Reason J, Wagenaar P, Bentley M, Primrose M, Visser J. (1994) Tripod-Delta: proactive approach to enhanced safety. Journal of Petroleum Technology **40**(1994): 58-62.

Institute for Safe Medication Practices (2000) A call to action: Eliminate hand written prescriptions within three years. Electronic prescribing can reduce medication errors., Institute for Safe Medication Practices

Institute of Medicine (1999) To Err is Human: Building a Safer Health System. Committee of Health Care in America, Institute of Medicine, Washington.

Institute of Medicine (2001) Crossing the Quality Chasm, Institute of Medicine, Washington.

Janis IL. (1972) Victims of Groupthink. Boston, Houghton-Mifflin.

Jarman H, Jacobs E., Zielinski V (2002) Medication study supports registered nurses competence for single checking. International Journal of Nursing Practice **8**(6): 330-335.

Jha AK, Kuperman GJ, Teich JM, Leape L, Shea B, Rittenberg E, Burdick E, Seher DL, Vander Vliet M, Bates DW (1998). Identifying adverse drug events. Journal of the American Medical Association **5**(3): 305-313.

Johnson CW, Holloway CM (2003) On the over-emphasis of human 'error' as a cause of aviation accidents: systemic failures and human error in US NTSB and Canadian TSB Aviation Reports. http://www.dcs.gla.ac.uk/~johnson Accessed 5.11.05

Johnson D (2001) How the Atlantic barons learnt teamwork. British Medical Journal **322**: 563.

Joint Commission on Accreditation of Health Care Organisations (2006) Identifying risks in medication use process, 6 (1). Medication Station. USA**:** Part 1 page 4.

Jones EE, Harris VA. (1967) The attribution of attitudes. Journal of Experimental Social Psychology **3**: 1-24.

Jones KJ, Cochran G, Hicks RW, Mueller KJ. (2004) Translating research into practice: voluntary reporting of medication errors in critical access hospitals. The Journal of Rural Health **20**(4): 335-343.

Kahneman D, Tversky A (1972) Subjective probability: a judgement of representativeness. Cognitive Psychology **3**(3): 430-54.

Kane-Gill SL, Devlin JW. (2006) Adverse event reporting in intensive care units: a survey of current practices. The Annals of Pharmacotherapy **40**: 1267-1273.

Kaplan H, & Barach P. (2002) Incident Reporting: science or protoscience? Ten years later. Quality and Safety in Health Care **11**: 144-5.

Kaplan HS, Fastman, BR. (2003) Organisation of event reporting data for sense making and system improvement. Quality and Safety in Health Care **12**

(Supplement ll): ii68-ii72.

Karsh B, Hamilton Escoto K, Beasley JW, Holden RJ. (2006) Toward a theoretical approach to medical error reporting system and design. Applied Ergonomics **37**: 283-295.

Kaushal R, Bates, DW, Landrigan, C, McKenna, KJ, Clapp, MD, Federico, F, Goldmann, DA. (2001) Medication errors and adverse drug events in paediatric inpatients. Journal of the American Medical Association **285**: 2114-2120.

Kazoaka T, Ohtsuka K, Ueno K, Mori M. (2007) Why nurses make medication errors: a simulation study. Nurse-Education Today **27**(4): 312-317.

King's College Hospital (2006) Personal Communication 22.3.06 with Risk Management Department, London.

Kingston MJ, Evans SM, Smith BJ, Berry JG. (2004) Attitudes of doctors and nurses towards incident reporting: a qualitative analysis. Medical Journal of Australia **181**(1): 36-39.

Kivlahan C, Sangster W, Nelson K, (2002) Developing a comprehensive electronic adverse event reporting system in an academic health center. Joint Commission Journal on Quality Improvement **28**: 583-94.

Kohn LT, Corrigan JM, Donaldson MS. (2000) To Err is Human: Building a Safer Health System. Institute of Medicine and Committee on Quality of Health Care in America, National Academy Press.

Kostopoulou O. (2006) From cognition to the system: developing a multi-level taxonomy of patient safety on general practice. Ergonomics **49** (5) 486-502. Special Patient Safety Issue.

Kozer E, Scolnik D, Macpherson A, Keays T, Shi K, Luk T, Koren G. (2002) Variables associated with medication errors in paediatric emergency medicine. Pediatrics **110**(4): 737-742.

Kunac DL, Reith DM, Kennedy J, Austin NC, Williams SM. (2006) Inter and intra-rater reliability for classification of medication-related events in paediatric inpatients. Quality & Safety in Health Care **15**: 196-201.

Kuzel AJ, Woolf SH, Engel JD, Gilchrist VJ, Frankel RM, Laveist TA, Vincent C. (2003) Making the case for a qualitative study of medical errors in primary care. Qualitative Health Research **13**(6): 643-80.

LaBerge D, Samuels SJ. (1974) Towards a theory of automatic information processing in reading. Cognitive Psychology **6**(293-323).

Last J. (2004) Personal Communication 4.7.04 with Aviation Safety Officer at Britannia Airlines.

Lawton R. (1998) Not working to rule: understanding procedural violations at work. Safety Science **28**: 77-95.

Lawton R. (2006) Personal Communication with Senior Lecturer. 7.6.06. Institute of Psychology, University of Leeds.

Lawton R. Parker D. (1998) Individual Differences in Accident Liability: a review

and integrative approach. Human Factors **40**(4): 655-71.

Lawton R, Parker D. (2002) Barriers to incident reporting in a healthcare system. Quality and Safety in Health Care **11**: 15-18.

Lawton R, Ward NJ. (2005) A systems analysis of the Ladbroke Grove rail crash. Accident Analysis and Prevention **37**(2): 235-44.

Leape L. (1994) Error in medicine. Journal of the American Medical Association **272**: 1851-57.

Leape L. (2002) Reporting of adverse events. New England Journal of Medicine **347**(20): 1633-8.

Leape L. (2004) Human factors meets health care: the ultimate challenge. Ergonomics in Design **Summer**: 6-12.

Leape L, Bates D.W, Cullen D.J, Cooper J, Demonaco HJ, Gallivan T, Hallisey R, Ives J, Laird N, Laffel G, Nemeskal R, Petersen L.A, Porter K, Servi D, Shea B.F, Small S.D, Sweitzer B.J, Thompson T, Vander Vleit M. (1995) Systems Analysis of Adverse Drug Events. Journal of the American Medical Association **274**(1): 35-43.

Leape L, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H. (1991) The nature of adverse events in hospitalised patients. Results of the Harvard Medical Practice Study ll. New England Journal of Medicine **324**(6): 377-384.

Leape L, Lawthers AG, Brennan TA, Johnson WG. (1993) Preventing medical injury. Quality Review Bulletin **19**: 144-9.

Legard R, Keegan J, Ward K. (2003) In-depth interviews. In Ritchie J, Lewis J. Qualitative Research Practice. p138-169. London, Sage.

Leigh JP, Marcin JP, Miller TR. (2004) An estimate of the US government's undercount of non-fatal occupational injuries. Journal of Occupational and Environmental Injuries **46**(1): 10-18.

Lerner MJ. (1970) The desire for justice and reactions to victims. In Berkowitz L,McCauley J. Altruism and Helping Behaviour. P205-229. New York, Academic Press.

Lesar TS, Briceland L, Delcoure K, Parmalee JC, Masta-Gornic V, Pohl H. (1990) Medication prescribing errors in a teaching hospital. Journal of the American Medical Association **263**: 2329-2334.

Lesar TS, Briceland L, Stein DS (1997) Factors related to error in medication prescribing. Journal of the American Medical Association **277**: 321-317.

Lewis J, Ritchie J. (2003) Generalizing from qualitative research. In Ritchie J, Lewis J. Qualitative Research Practice. P.263-286. London, Sage.

Lewis RQ, Fletcher M. (2005) Implementing a national strategy for patient safety: lessons from the National Health Service in England. Quality & Safety in Health Care **14**: 135-139.

Lilford R, Mohammed M, Braunholtz D, Hofer TP. (2003) The measurement of active errors: methodological issues. Quality & Safety in Health Care **12**

(Supplement ll): ii8-ii12.

Lincoln YS, & Guba EG. (1985) Naturalistic Inquiry. Newbury Park, Sage.

Lucas DA. (1987) Human performance data collection in industrial systems. . London, IBC Technical Services.

Macfie R. (1997 Rewarding Safety. Safeguard **March/April**.

Maidment ID, Lelliott P, Paton C (2006) Medication errors in mental healthcare: a systematic review. Quality and Safety in Health Care **15**: 409-413.

Maillard N, Stirling S, Lilford R, Johal A, Gilbert N (2005) Patient safety: an unsystematic review and bibliography.
www. Pcpoh.bham.ac.uk/publichealth/psrp/Pdf/patientsafetybibliography Accessed 8.4.07

Malpass A, Helps SC, Runciman WB. (1999a) An analysis of Australian adverse drug events. Journal of Quality in Clinical Practice **19**: 27-30.

Malpass A, Helps SC Sexton EJ Maile D Runciman WB (1999b) A classification for adverse drug events. Journal of Quality in Clinical Practice **19**: 23-26.

Mason J. (1996) Qualitative Researching. London, Sage.

McArdle D, Burns N, Ireland A, (2003) Attitudes and beliefs of doctors towards medication error reporting. International Journal of Health Care Quality Assurance **16**(7): 326-333.

McDonald CJ, Weiner M, Hui SL. (2000) Deaths due to medical errors are exaggerated. Journal of the American Medical Association **284**: 93-95.

Medvedev G. (1989) The Truth About Chernobyl. New York, Tauris & Gold.

Merry AF, Peck DJ. (1995) Anaesthetists, errors in drug administration and the law. New Zealand Medical Journal **108**: 185-7.

Miller MR, Clark JS, Lehmann CU (2006) Computer based medication error reporting: insights and implications. Quality & Safety in Health Care **15**: 208-213.

Miller MR, Robinson KA, Lubomski LH, Rinke ML, Pronovost PJ. (2007) Medication errors in paediatric care: a systematic review of epidemiology and an evaluation of evidence supporting reduction strategy recommendations. Quality & Safety in Health Care **16**: 116-126.

Miyata Y, Norman DA (1986) Psychological Issues in Support of Multiple Activities. In Draper. SW, Norman DA. User-centred System Designs.. Hillsdale, Lawrence Erlbaum Associates**:** 265-284.

Morimoto T, Gandhi TK, Seger AC, Hsieh TC, Bates DW. (2004) Adverse drug events and medication errors: detection and classification methods. Quality and Safety in Health Care **13**: 306-314.

Morse J. (1995) The significance of saturation. Qualitative Health Research **5**: 147-9.

Morse JM. (1994) Emerging from the data: the cognitive processes of analysis in

qualitative inquiry. Critical Issues in Qualitative Research Methods. Morse JM. Thousand Oaks, Sage**:** 23-43.

Mrayyan MT, Shishani K, Al-Faouri I. (2007) Rate, causes and reporting of medication errors in Jordan: nurses' perspectives. Journal of Nursing Management **15**: 659-670.

Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P. (1998) Qualitative research methods in health technology assessment: a review of the literature. Health Technology Assessment. NHS R&D HTA Programme. University of Southampton.

Nakajima K, Kurata Y, Takeda H (2005) A web-based reporting system and multi-disciplinary system and multi-disciplinary collaborative project for patient safety in a Japanese hospital. Quality & Safety in Health Care **14**: 123-9.

National Audit Office (2005) A Safer Place for Patients. London, Comptroller and Auditor General. National Audit Office.

National Coordinating Council for Medication Error Reporting and Prevention (1998) Taxonomy of Medication Errors. NCCMERP. Rockville, Maryland, USA. Also available at: www.nccmerp.org/

National Expert Advisory Group on Safety & Quality in Australian Health Care (1999) Implementing Safety and Quality in Health Care. Canberra, Australia, Commonwealth of Australia Department of Health & Aged Care (49).

National Patient Safety Agency (2004) Seven steps to patient safety: an overview guide for NHS staff. London, NPSA.

National Patient Safety Agency (2005a) Building a memory: preventing harm, reducing risks and improving patient safety. London, NPSA.

National Patient Safety Agency. (2005b) Staff Reports to National Reporting and Learning System. www.npsa.nhs.uk/staffreports Accessed 18.8.05

National Patient Safety Agency (2007a) Safety in Doses: improving the use of medicines in the NHS. London, NPSA.

National Patient Safety Agency Observatory Report (2007b) Slips, trips and falls in hospital. www.npsa.nhs.uk/site/media/documents/2387_PSO_fallsweb_x.pdf Accessed 23.3.07

Naylor R. (2002) Medication errors: lessons for education and healthcare. Oxford, Radcliffe Medical Press.

Nebeker JR, Barach P, Samore MH. (2004) Clarifying adverse drug events: a clinician's guide to terminology, documentation, and reporting. Annals of Internal Medicine **140**: 795-801.

New Oxford English Dictionary (2001) Oxford, Oxford University Press.

New York State Department of Health (2002) New York Patient Occurrence Reporting and Tracking System: Annual Report 2000-2001. New York, New York State Department of Health.

NHS Centre for Reviews & Dissemination (2001) CRD Report 4. Reviews of

Research on Effectiveness: Guidance for those Carrying Out or Commissioning a Review. York, University of York.

Nickerson RS. (1998) Confirmation bias: a ubiquitous phenomenon in many guises. Review of General Psychology **2**(2): 175-220.

Norman DA. (1981) Categorization of action slips. Psychological Review **88**: 1-15.

Norman DA. (1988) The Psychology of Everyday Things. New York, Basic Books.

Norman DA, Bobrow DG. (1976) On the analysis of performance operating characteristics. Psychological Review **83**(508-510).

O'Conner W. (2006) Personal Communication 28.3.06 with William O'Conner, at National Centre for Social Research.

Olsen S, Neale G, Schwab K, Psaila B, Patel T, Chapman EJ, Vincent C. (2007) Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real time record review may all have a place. Quality & Safety in Health Care **16**: 40-44.

O'Neil A, Petersen L, Cook E, Bates D, Lee T, Brennan T. (1993) Physician reporting compared with medical record review to identify adverse medical events. Annals of Internal Medicine **119**: 370-6.

Oppenheim AN. (1992) Questionnaire design, interviewing and attitude measurement. London, Continuum.

Orser BA, Chen RJ, Yee DA. (2001) Medication errors in anaesthetic practice. Canadian Journal of Anesthesia **48**: 139-146.

O'Shea E. (1999) Factors contributing to medication errors: a literature review. Journal of Clinical Nursing **8**: 496-504.

Pape T. (2001) Searching for the final answer: factors contributing to medication administration errors. Journal of Continuing Education in Nursing **32**(4): 152-160.

Parker D Lawton R. (2002) Managing medical mishaps: learning lessons from industry. In Cashman JN Frances RM. Recent Advances in Anaesthesia & Intensive Care. P. 209-221.Cambridge, Cambridge University Press**.**

Parker D, Lawton R. (2003) Psychological contribution to the understanding of adverse events in health care. Quality & Safety in Health Care **12**(6): 453-7.

Parker D, Lawton R. (2006) Psychological approaches to patient safety. In Walshe K. Boaden R. Patient Safety: Research into Practice. Maidenhead, Berkshire, Open University Press.

Parkinson's Disease Society (2006) 'Get it on time' Campaign for prompt medication administration in Parkinson's Disease patients. London, Parkinson's Disease Society.

Patel VL, Kaufman DR. (1998) Medical informatics and the science of cognition. Journal of the American Medical Informatics Association **5**(493-502).

Patton MQ. (1999) Enhancing the quality and credibility of qualitative analysis. Health Services Research **34**(5(2)): 1189-1208.

Perneger TV. (2005) The Swiss Cheese Model of Safety Incidents: are there holes in the metaphor? www.biomedcentral.com/1472-6963/5/71 Accessed 1.2 07.

Perrow C. (1984) Normal Accidents: Living with High Risk Technologies. Princeton, Princeton University Press.

Perrow C. (1999) Organising to reduce the vulnerabilities of complexity. Journal of Contingencies and Crisis Management **7** (3): 150-5.

Peterson GM, Wu MSH, Bergin JK. (1999) Pharmacists' attitudes towards dispensing errors: their cause and prevention. Journal of Clinical Pharmacy and Therapeutics **24**(57-71).

Philips L. (1998) Combining quantitative and qualitative approaches to social research in human geography. Environment & Planning **30**: 261-276.

Pidgeon NF (1996). Safety Culture and Risk Management in Organisations. Journal of Cross Cultural Psychology **22**: 129-140.

Pimble J, Toole S (1982) Analysis of accident reports. Ergonomics **25**(11): 967-979.

Pope A. (1711) An essay on criticism. Oxford Concise Dictionary of Quotations. Partington A. Oxford, Oxford University Press. **3rd Edition:** Line 525.

Pope C, Ziebland S Mays N. (2000) Qualitative research in healthcare: analysing qualitative data. British Medical Journal **320**: 114-6.

Potylicki MJ, Kimmel SR, Ritter M, Capuano T, Gross L, Riegel-Gross K, Panik A. (2006) Non-punitive medication error reporting. Journal of Nursing Administration **36** (7/8): 370-376.

Prior L. (2004) Doing things with documents. In Silverman D. Qualitative Research: methods, theory and practice. P76-94. London, Sage.

Pronovost P, Weast B, Schwarz M. (2003) Medication reconciliation: a practical tool to reduce the risk of medication errors. Journal of Critical Care **18**(4): 201-205.

Pronovost PJ, Nolan T, Zeger S, Miller M, Rubin H. (2004) How can clinicians measure safety and quality in acute care? The Lancet **363**: 1061-1067.

Prosser T. (2003) Accidents will happen. Fire **96**: 23-24.

Prot S, Eudes Fontan J, Alberti C, Bourdon O, Farnoux C, Macher MA, Foureau A, Faye A, Beaufils F, Gottot S, Brion F. (2005) Drug administration errors and their determinants in pediatric in-patients. International Journal for Quality in Health Care **17**(5): 381-9.

Radcliffe NM, Klein WMP. (2002) Dispositional, Unrealistic, and Comparative Optimism: Differential Relations with the Knowledge and Processing of Risk Information and beliefs about Personal Risk. Personality and Social Psychology Bulletin **28** (6): 836-846.

Rasmussen J. (1982) Human error: a taxonomy for describing human malfunction in industrial installations. Journal of Occupational Accidents **4**: 311-313.

Rasmussen J. (1990) Human error and the problem of causality in analysis of accidents. Philosophical Transactions of the Royal Society of London **B 327**: 449-462.

Rasmussen J. (1993) Learning from experience? Some research issues in industrial risk management. In Wilpert B, Qvale T. Reliability and Safety in Hazardous Work Systems. Hove, Lawrence Erlbaum.

Rasmussen J. (1997) Risk management in a dynamic society. Safety Science **27**: 183-214.

Rasmussen J. (1999) The concept of human error: is it useful for the design of safe systems in health care? Risk and Safety in Medicine d. M. B. Vincent C. London, Elsevier.

Rasmussen J, Jensen A. (1974) Mental procedures in real life tasks: a case study of electronic trouble shooting. Ergonomics **17**(17): 293-307.

Reason JT. (1974) Man in Motion. London, Weidenfield & Nicholson.

Reason JT. (1990) Human Error. Cambridge, Cambridge University Press.

Reason JT. (1991) Too little and too late: a commentary on accident and incident reporting systems. In Van Der Schaaf TW, Lucas DA, Hale AR. Near miss reporting as a safety tool. London, Butterworth Heinemann.

Reason JT. (1997) Managing the Risks of Organisational Accidents. Aldershot, Ashgate.

Reason JT. (2000) Human error, models and management. British Medical Journal **320**(7237): 768-770.

Reason JT. (2004) Beyond the organisational accident: the need for 'error wisdom' on the frontline. Quality & Safety in Health Care **13** (Supplement II): ii28-33.

Ridge KW, Jenkins DB, Noyce PR, Barber ND. (1995) Medication errors during hospital drug rounds. Quality in Heath Care **4**: 240-243.

Ritchie J. (2003) The Applications of Qualitative Methods to Social Research. In Ritchie J, Lewis J. Qualitative Research Practice. P24-46. London, Sage.

Ritchie J, Lewis J, Elam G. (2003a) Designing and Selecting Samples. In Ritchie J. Lewis J. Qualitative Research Practice. P.77-108. London, Sage**.**

Ritchie J, Spencer L, O'Connor W. (2003b) Carrying out qualitative analysis. In Ritchie J. Lewis J. Qualitative Research Practice. p.219- 262. London, Sage**.**

Ritchie J, Spencer L. (1994) Qualitative data analysis for applied policy research. In Bryman A, Burgess RG. Analysing qualitative data. P173-194. London, Routledge.

Roberts DE, Spencer MG, Bowden S. (2002) An analysis of dispensing errors in NHS hospitals. International Journal of Pharmacy Practice **10** (Supplement): R6.

Robinson AR, Hohmann KB, Rifkin JI, et al. (2002) Physician and public opinion on quality of healthcare and the problem of medical errors. Archives of Internal Medicine 162: 2186-2190

Robson C. (2002) Real World Research. London, Blackwell Publishing.

Rosenthal J, Booth M, Barry A. (2001) Cost Implications of State Medical Error Reporting programmes: a briefing paper. Portland, Maine, National Academy for State Health Policy.

Rosenthal M. (1999) How doctors think about medical mishaps. In Rosenthal M, Mulcahy L, Lloyd-Bostock S. Medical Mishaps. P141-153. Buckingham, Open University Press.

Ross LM, Wallace, J, Paton, JY. (2000) Medication errors in a paediatric teaching hospital in the UK: five years operational experience. Archives of Disease in Childhood **83**: 492-497.

Ross SD. (2001) Drug-related adverse events. Archives of Internal Medicine **161**(April 23rd): 1041-1046.

Rozich JD, Haraden CR, Resar RK. (2003) Adverse event trigger tool a practical methodology for measuring medication-related harm. Quality & Safety in Health Care **12**: 194-200.

Rozich JD, Resar RK. (2001) Medication safety: one organisation's approach to the challenge. Journal of Clinical Outcomes and Management **8**(10): 27-34.

Rubin G, George A, Chinn DJ, Richardson C. (2003) Errors in general practice: development of an error classification and pilot study of a method for detecting errors. Quality & Safety in Health Care **12**: 443-447.

Runciman WB. (1993) Qualitative versus quantitative research - balancing cost, yield and feasibility. Anaesthesia & Intensive Care **21**: 502-5.

Runciman WB, Helps SC, Sexton EJ, Malpass A. (1998) A classification for incidents and accidents in the health-care system. Journal of Quality in Clinical Practice **18**: 199-211.

Runciman WB, Merry AF, McCall-Smith A. (2001) Improving patients' safety by gathering information. British Medical Journal **323**: 298.

Runciman WB & Merry WB (2003) A tragic death: a time to blame or a time to learn? Quality and Safety in Health Care **12**: 321-2.

Runciman WB, Merry AF Tito F (2003a) Error, blame, and the law in health care - an Antipodean perspective. Annals of Internal Medicine **138**(12): 974-9.

Runciman WB, Roughead EE, Semple SJ, Adams RJ. (2003b) Adverse drug events and medication errors in Australia. International Journal of Quality in Health Care **15**(Supplement 1): i49-i59.

Runciman WB, Sellen A, Webb R, Williamson JA, Currie M, Morgan C, Russell WJ. (1993) Errors, incidents and accidents in anaesthetic care. Anaesthesia and Intensive Care **21**(5): 506-509.

Sandelowski M. (1986) The problem of rigour in qualitative research. Advances in Nursing Science **8**(3): 27-37.

Sandelowski M. (1993) Rigor or rigor mortis: the problem of rigor in qualitative research revisited. Advances in Nursing Science **16**(2): 1-8.

Sanghera IS, Franklin BD, Dhillon S. (2007) The attitudes and beliefs of healthcare professionals on the causes and reporting of medication errors in a UK intensive care unit. Anaesthesia **62**: 53-61.

Sari A, Sheldon TA, Cracknell A, Turnbull A. (2007) Sensitivity of routine reporting systems for reporting safety incidents in an NHS hospital: retrospective case note review. British Medical Journal **334**: 79.

Schioler T, Lipczak H, Pedersen BL, Mogenson TS, Bech KB, Stockmarr A, (2001) Incidence of adverse events in hospitals. Retrospective study of medical records. Ugeskr Laeger **163**(39): 5370-80.

Schulmeister L. (1999) Chemotherapy medication errors: descriptions, severity, and contributory factors. Oncology Nursing Forum **26**(6): 1033-1941.

Scobie S. (2007) Linking to the National Reporting & Learning System. Clinical Incident Reporting. Royal Society, London, Health Care Events.

Scott J. (1990) A Matter of Record: documentary sources in social research. Cambridge, Polity Press.

Schwandt T. (1997) Qualitative Inquiry: a dictionary of terms. Thousand Oaks, Sage.

Seale C. (2004) Researching Society and Culture. London, Sage.

Selbst S, Fein, JA, Osterhoudt, K, Ho, W. (1999) Medication errors in a paediatric emergency department. Pediatric Emergency Care **15**(1): 1-4.

Shaw R, Drever F Hughes H Osborn S Williams S. (2005) Adverse events and near miss reporting in the NHS. Quality and Safety in Health Care **14**: 279-283.

Shojania KG, Duncan BW, McDonald KM, Wachter RM. (2001) Making Health Care Safer: a critical analysis of patient safety practices. Technology Assessment No. 43 (01-e058). www.ahrq.gov/clinic/ptsafety/. Accessed 4.6.05

Silverman D. (1985) Qualitative methodology and sociology. Aldershot, Gower.

Silverman D. (2000) Doing Qualitative Research: a practical handbook. London, Sage.

Silverman D. (2001) Interpreting Qualitative Data. London, Sage.

Simpson JH, Lynch, R, Grant, J, Alroomi, L. (2004) Reducing medication errors in the neonatal intensive care unit. Archives of Disease in Childhood Fetal Neonatology Edition **89**: F480-482.

Sistrom CL, Honeyman-Buck J. (2005) Free text versus structured format: information transfer efficiency of radiology reports. American Journal Of Roentgenology **185**(3): 804-811.

Slovic P, Fischoff B. (1977) On the psychology of experimental surprises. Journal of Experimental Psychology: Human Performance Perception **3**: 544-51.

Smetzer JL, Vaida AJ, Cohen MR, Tranum D, Pittman MA, Armstrong CW. (2003) Findings from the ISMP Medication Safety Self-Assessment for Hospitals. Joint

Commission on Quality and Patient Safety **29**(11): 596-597.

Smith D. (2000) On a wing and a prayer? Exploring the human components of technological failure. Systems Research and Behavioural Science **17**: 543-559.

Snape D, Spencer L. (2003) The Foundations of Qualitative Research. In Ritchie J. Lewis J. Qualitative Research Practice. p.1-23. London, Sage.

Spencer L, Ritchie J, O'Conner W. (2003) Analysis: practices, principles and processes. In Ritchie J, Lewis J. Qualitative Research Practice. p199-218. London, Sage.

Spencer MG, Smith AP (1993) Multi-centred study of dispensing errors in British hospitals International Journal of Pharmacy Practice **2**: 142-146.

Stanhope N, Crowley-Murphy M Vincent C, O'Connor AM, Taylor-Adams SE. (1999) An evaluation of adverse incident reporting. Journal of Evaluation in Clinical Practice **5**: 5-12.

Steel K, Gertman PM, Crescinzi C, Anderson J. (1981) Iatrogenic illness in a general medical service at a university hospital. New England Journal of Medicine **304**: 638-642.

Sternberg RJ. (2003) Cognitive Psychology. Belmont, California, Thomson-Wadsworth.

Storch M. (2005) Personal communication 18.4.05 with co-Author National Co-ordinating Council for Medication Error and Prevention, Rockville, Maryland.

Strauss A, Corbin J. (1990) Basics of Qualitative Research. Grounded Theory: procedures and techniques. London, Sage.

Strauss AC. (1987) Qualitative Analysis for Social Scientists. Cambridge, Cambridge University Press.

Subbe CP, Gao H, Harrison DA. (2007) Reproducability of physiological track and trigger warning systems for identifying at risk patients on the ward. Intensive Care Medicine **33** 619-624

Suresh GS, Horbar JD, Plsek P, Gray J, Edwards WH, Shiono PH, Ursprung R. (2004) Voluntary anonymous reporting of medical errors for neonatal intensive care. Pediatrics **113**: 1609-1618.

Sutcliffe K, Lewton E Rosenthal M. (2004) Communication failures: an insidious contributor to medical mishaps. Academic Medicine **79**(2): 186-194.

Symonds T, Shoesmith I (2007) Pilots raise fears over fatigue. www.bbc.co.uk/1/low/uk/6236810 Accessed 30.6.07

Tamuz M. (1994) Developing organisational safety information systems for monitoring potential dangers. Advancement of systems based methods for design and operation of technological systems and processes, San Diego, California, Galen Press.

Tamuz M, Harrison MI. (2006) Improving Patient Safety in Hospitals: Contributions of High Reliability Theory and Normal Accident Theory. Health Services Research **41**(4): 1654-76.

Tamuz M, Thomas EJ Franchois KE. (2004) Defining and classifying medical error: lessons for patient safety reporting systems. Quality and Safety in Health Care **13**: 13-20.

Tang FI, Sheu SJ, Yu S, Wei IL, Chen CH. (2007) Nurses relate the contributory factors in medication errors. Journal of Clinical Nursing **16**(3): 447-457.

Taxis K, & Barber N. (2003a) Ethnographic study of incidence and severity of intravenous drug errors. British Medical Journal **326**: 684-7.

Taxis K, Barber N (2003b) Causes of intravenous medication errors: an ethnographic study. Quality & Safety in Health Care **12**: 343-347.

Taxis K, Dean, B, Barber N (1999) Hospital drug distribution systems in the UK and Germany - a study of medication errors. Pharmacy World & Science **21**(1): 25-31.

Taylor JA, Brownstein D, Christakis DA, Blackburn S, Strandjord TP, Klein EJ, Shafii J. (2004) Use of incident reports by physicians and nurses to document medical errors in pediatric patients. Pediatrics **114**(3): 729-735.

Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena TBS, Williams EJ, Mason HK, Weiler PC, Brennan TA. (2000) Incidence and types of adverse events and negligent care in Utah & Colorado. Medical Care **38**(3): 261-71.

Thomas EJ, Studdert DM, Brennan TA. (2002) The Reliability of Medical Record Review for Estimating Adverse Event Rates. Annals of Internal Medicine **136**(11): 812-6.

Thomas EJ, Sexton JB, Helmriech RL. (2003) Discrepant attitudes about teamwork among critical care nurses and physicians. Critical Care Medicine **31**(3): 956-959.

Tissot E, Cornette C, Demoly P, Jacquet M, Barale F, Capellier G. (1999) Medication errors at the administration stage in an intensive care unit. Intensive Care Medicine **25**(4): 353-9.

Tissot E, Cornette C, Limat S, Mourand J, Becker M, Etievent JP, Dupond JL, Jacquet M, Woronoff-Lemsi M. (2003) Observational study of potential risk factors of medication administration errors. Pharmacy World Science **25**(6): 264-8.

Toft B. (2001) External Inquiry into the adverse event that occurred at Queen's Medical Centre 4.1 01. Nottingham. Department of Health, HMSO.

Triandis H. (1977) Interpersonal Behaviour. California, Brooks Cole.

Tucker AL, Edmondson AC. (2003) Why hospitals don't learn from failures: organisational and psychological dynamics that inhibit system change. California Management Review **45**(2): 55.

Turner BA. (1978) Man-Made Disasters. London, Wykeham.

Turner BS. (1992) Medical Power and Social Knowledge. London, Sage.

Tuttle D, Holloway R Baird T Sheehan B Skelton WK. (2004) Electronic reporting to improve patient safety. Quality and Safety in Health Care **13**: 281-286.

Tversky A, Kahneman D (1973) Availability: a heuristic for judging frequency and

probability. Cognitive Psychology **5**: 207-232.

United States Government (2003) Columbia Accident Investigation Board. Volume 1. Washington, DC, United States Government**.**

University of Manchester & National Patient Safety Agency (2006) Manchester Patient Safety Framework (*MaPSaF*). Manchester, University of Manchester / NPSA.

Uribe CL, Pathak DS, Schweikhart SB. (2001) Factors influencing medical error reporting in an academic medical center. Abstracts of the Academic Health Service Research & Health Policy Meeting **18**: 39.

Uribe CL, Schweikhart, SB, Pathak, DS, Gail BM, Reed Fraley R. (2002) Perceived barriers to medical error reporting: an exploratory investigation. Journal of Healthcare Management **47**: 263-79.

Van den Bemt PMLA, Egberts ACG, Lenderink AW, Verzijl JM, Simons KA, van der Pol WSCJM, Leufkens HGM. (2000) Risk factors for the development of adverse drug events in hospitalised patients. Pharmacy World and Science **22**(2): 62-66.

Vaughan D. (1996) The Challenger Launch Decision. Chicago, University of Chicago press.

Vere-Jones E. (2005) Doctors loathe to report slip-ups. Hospital Doctor: 7.

Vincent C, Coulter A (2002). Patient Safety: what about the patient? Quality & Safety in Health Care **11**: 76-80.

Vincent C. (2006) Patient Safety. London, Elsevier.

Vincent C. (2007) Incident Reporting and Patient Safety. British Medical Journal **334**: 51.

Vincent C, Neale G, Woloshynowych M. (2001) Adverse events in British hospitals: preliminary retrospective record review. British Medical Journal **322**: 517-519.

Vincent C, Reason JT. (1999) Human factors approach in medicine. In Rosenthal M, Mulcahy L, Lloyd-Bostock S. Medical Mishaps. Buckingham, Open University Press.

Vincent C, Stanhope, N, Crowley-Murphy, M. (1998) Reasons for not reporting adverse events: an empirical study. Journal of Evaluation in Clinical Practice **5**(1): 13-21.

Vincent C, Taylor-Adams S, Chapman EJ, Hewett D, Prior S, Strange P, Tizard A. (2000) How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management Protocol. British Medical Journal **320**: 777-81.

Vira T, Colquhoun M, Etchells E. (2006) Reconcilable differences: correcting medications at hospital admission and discharge. Quality & Safety in Health Care **15**: 122-126.

Wachter RM. (2004) The end of the beginning: patient safety five years after to err is human. The Commonwealth Fund: www.commonwealthfund.org/publications/publications_show.htm?doc_id=250749

Accessed 11.6.06

Wagenaar WA, Groeneweg J (1987) International Journal of Man-Machine Studies. 27 **587-598**.

Wakefield BJ, Blegen MA, Uden-Holman T, Vaighan T, Chrsichilles E, Wakefield DS. (2001) Organisational culture, continuous quality improvement and medication administration error reporting. American Journal of Medical Quality **16**(4): 128-134.

Wakefield DS, Wakefield BJ, Uden-Holman T. (1996) Perceived barriers in reporting medication administration errors. Best Practice in Benchmarking Health Care **1**: 191-197.

Wakefield DS, Wakefield BJ, Uden-Holman T, Blegen MA. (1998) Nurses' perceptions of why medication errors occur. MedSurg Nursing **7**(1): 39-43.

Wakefield DS, Wakefield BJ, Uden-Holman T, Borders T, Blegen M, Vaughan T. (1999a) Understanding and comparing differences in reported medication administration error rates. American Journal of Medical Quality **14**(2): 73-80.

Wakefield DS, Wakefield BJ, Uden-Holman T, Borders T, Blegen M, Vaughan T. (1999b) Understanding why medication errors may not be reported. American Journal of Medical Quality **14**(2): 81-88.

Wald H, & Shojania, KG. (2003) Incident Reporting. Building foundations, Reducing Risk Agency for Healthcare Research & Quality. Rockville, Maryland. Agency for Healthcare Research & Quality

Walji M, Johnson-Throop KJ, Malin JT, Zhang J. (2004) The Case for Persuasive Interruptions in Healthcare. www.interruptions.net/literature/Walji-Medinfo04.pdf. Accessed 1.12.07

Walker SB, Lowe MJ. (1998) Nurses' views on reporting medication errors. International Journal of Nursing Practice **4**: 97-102.

Walshe K. (2000) Adverse events in health care: issues in measurement. Quality in Health Care **9**: 47-52.

Walshe K. (2007) Understanding what works - and why - in quality improvement: the need for theory-driven evaluation. International Journal for Quality in Health Care **19**(2): 57-59.

Walshe K, Boaden R. (2006) Conclusion and the way forward. In Walshe K, Boaden R. Patient Safety: Research into Practice. Maidenhead, Open University Press**:** 217-231.

Waring J. (2004) A qualitative study of the intra-hospital variations in incident reporting. International Journal for Quality in Health Care **16**(5): 347-352.

Waring J. (2005) Beyond blame: cultural barriers to medical incident reporting. Social Science and medicine **60**(9): 1927-1935.

Webb RK, Currie M, Morgan CA. (1993) The Australian Incident Monitoring Study. Anaesthesia and Intensive Care **21**: 520-528.

Weick K E, Sutcliffe KM. (2001) Managing the unexpected: assuring high performance in an age of complexity. San Francisco, Jossey-Bass.

Weick KE. (1987) Organisational Culture as a Source of High Reliability. California Management Review **XXIX**(2): 112-127.

Weick KE. (1991) The vulnerable system: an analysis of the Tenerife air disaster. In Frost PJ. Reframing Organisational Culture. London, Sage.

Weingart SN, Wilson RM, Gibberd RW, Harrison B. (2000) Epidemiology of medical error. Quality & Safety in Health Care **320**: 774-7.

West E. (2000) Organisational sources of safety and danger: sociological contributions to the study of adverse events. Quality in Health Care **9**: 120-126.

Westrum R. (2004) A typology of organisational cultures. Quality & Safety in Health Care **13** (Supplement ll): 22-7.

Westwood M, Rodgers M, Sowden A. (2002) Patient Safety: A Mapping of the Research Literature. York, NHS Centre for Reviews and Dissemination.

Wheeler SJ, Wheeler DW. (2005) Medication errors in anaesthesia and critical care. Anaesthesia **60**: 257-273.

Wilkinson S. (2004) Focus group research. In Silverman D. Qualitative Research: methods, theory and practice. p177-199. London, Sage.

Wilson DG, McArtney RG, Newcombe RG, McArtney RJ, Gracie J. (1998) Medication errors in paediatric practice: insights from a continuous quality improvement approach. European Journal of Pediatrics **157**(769-774).

Wilson RM, Runciman, WB, Gibberd, RW, Harrison BT, Newby L, Hamilton JD. (1995) The Quality in Australian Health Care Study. Medical Journal of Australia **163**: 458-471.

Woods DD Cook RI. (2003) Mistaking Error. In Hatlie MJ & Youngberg BJ. Patient Safety Handbook. Boston: Jones & Bartlett.

Woods DD, Cook RI. (1999) Perspectives on Human Error: Hindsight Biases and Local Rationality. In Durso F, Nickerson R, Schvanefelt J. Handbook of Applied Cognition.New York, Wiley.

Woods DD, Johannesen L, Cook RI, Sarter NB. (1994) Behind Human Error: Cognitive Systems, Computers and Hindsight. Wright-Patterson AirForce Base, Dayton, Ohio, Crew Systems Ergonomics Information and Analysis Centre.

Woodward S, Hill K, Adams S, (2004). Carrying out internal reviews of serious incidents. In Duffy D, Ryan T. New approaches to preventing suicide. London, Jessica Kingsley.

Woolever DR. (2004) The impact of a patient safety program on medical error reporting. Advances in Patient Safety **1**: 307-316.

World Health Organisation (2005) WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. World Alliance for Patient Safety. Geneva, WHO.

World Health Organisation (2006) World Alliance for Patient Safety: Forward Programme. Geneva, WHO.

Yu KH, Nation, RL, Dooley, MJ. (2005) Multiplicity of medication safety terms: definitions and functional meanings: when is enough enough? Quality and Safety in Health Care **14**: 358-363.

Zhang J, Patel VL Todd RJ Shortliffe EH. (2004) A cognitive taxonomy of medical errors. Journal of Biomedical Informatics **37**: 193-204.